NATIONAL BLOOD AUTHORITY
AUSTRALIA

NATIONAL REPORT ON THE ISSUE AND USE OF INTRAVENOUS IMMUNOGLOBULIN (IVIg)

Annual Report 2011-12

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Introduction

The purpose of this report is to provide an overview of the trends in the demand volume and cost of intravenous immunoglobulin (IVIg) from 2003-04 to 2011-12. IVIg is funded by the National Blood Authority (NBA) under the national blood arrangements. IVIg is an expensive blood plasma product that offers life-saving therapy and significant quality of life improvements for thousands of Australians. It is used to treat a broad range of conditions including applications in immunoglobulin replacement and immune modulation therapy.

IVIg is one of the major components of government expenditure on blood and blood products each year. Demand for IVIg continues to rise steadily, and Australian use of this product is amongst the highest when compared to international use on a per capita basis.

Governments have agreed to provide IVIg under the national blood arrangements for the conditions and uses described in the latest edition of *the Criteria for the clinical use of intravenous immunoglobulin in Australia (Criteria)* in Chapters 5, 6 and 7 (conditions for which there is reasonable evidence and/or clinical support for the use of IVIg therapy). IVIg funded under the national blood arrangements is not available to treat conditions identified in Chapter 8. For the purpose of this report a Disease Group is a medical condition within the *Criteria* and primary diagnosis (the condition) is a more specific diagnosis within the disease group.

Good stewardship of blood and blood products involves careful management of a unique resource across the health system in order to meet a growing health need at an affordable cost. This report aims to provide stakeholders with meaningful detail on IVIg demand and supply to assist in informed analysis and decision making.

The report draws on data from the Australian Red Cross Blood Service (Blood Service) Supply Tracking Analysis Recording System (STARS) database, which is maintained by the Blood Service as contracted authoriser and distributor of IVIg products. Information is also sourced from supply and invoicing data held in the NBA Integrated Data Management System (IDMS) on the delivery of products from the source commercial suppliers to the Blood Service under contracts managed by the NBA.

The report provides information at the national, and where appropriate, state and territory levels and also provides limited data on IVIg supplied under Direct Orders (DOs) which are paid for directly by jurisdictional or hospital arrangements. A list of acronyms and definitions is at **Appendix A** and further information on the background of IVIg supply and access policy in Australia is at **Appendix B.**

The NBA coordinates national supply and demand planning for blood and blood products including supply risk management; purchases blood and blood products on behalf of all Australian governments; develops and implements national strategies to encourage better governance, management and use of blood and blood products; and provides expert advice to support government policy development.

This report does not include Normal Immunoglobulin (NIg) or Subcutaneous Immunoglobulin (SCIg).

Highlights

Product supply under national blood arrangements

- In 2011-12 3.27 million grams of IVIg were issued under the national blood arrangements
- Total expenditure in 2011-12 for finished IVIg products was $204.4 million (approximately 22% of blood products expenditure under NBA arrangements), an increase of $19.4 million over 2010-11. This excludes the cost of collecting plasma for fractionation paid to the Blood Service
- Australia produced 78% of the IVIg used and 22% was imported
- Annual growth in issues of IVIg from 2010-11 to 2011-12 was 10.9%
- Average annual growth in issues of IVIg from 2003-04 to 2011-12 years was 11.5%
- A total of 12,127 patients were issued IVIg for 101,388 patient episodes compared to 11,438 patients and 93,893 patient episodes in 2010-11
- The 2011-12 national average of IVIg grams issued per 1000 head of population was 145.5
- Tasmania (TAS), Queensland (QLD), New South Wales (NSW) and the Australian Capital Territory (ACT) continued to have IVIg issued per 1000 head of population above the national average
- The number of patients receiving IVIg under national blood arrangements but recorded as not meeting the *Criteria* has fallen from 852 in 2008-09 to 22 patients in 2011-12

Clinical demand

- Neurology continued to show the fastest increase in demand for IVIg, more than doubling since 2006-07
- Acquired hypogammaglobulinaemia secondary to haematological malignancies is the condition for which the greatest percentage of IVIg was issued in 2011-12 (21.2%)

Demographics of IVIg patients

- The average number of new patients each quarter is over 1,000
- The very young and those over 70 years received more IVIg product than other age groups
- Median estimated year of birth for IVIg patients is 1953

Notes on data quality

Reconciliation of authorisation and supply data

The reconciliation of STARS and IDMS data indicates minor variances at a national level. In some cases these differences can be explained by product being ordered and recorded in STARS the month prior to product actually being issued.

Population

The Australian Bureau of Statistics (ABS) utilises a combination of series 3222.0 and 3101.0 for historical population and projections. The ABS population series 3201.0 (Population by Age and Sex, Australian States and Territories) ended June 2010. This was replaced by Australian Demographic Statistics (cat. No 3101.0). This series was utilised for earlier IVIg annual reports.

Patients

Care should be taken when interpreting the data relating to smaller states and territories as these can be materially influenced by small numbers of patients. Cross border usage has not been adjusted for in the data provided. This could impact on the grams per 1000 population calculations for states and territories such as the ACT, NT, SA and TAS.

Patients may receive product in more than one state and territory for example when they relocate from one to another. They will be counted as a patient in both those states and territories. However, the national patient count will only count them once as they are unique to Australia. This may result in the sum of the state and territory being greater than the national total.

Patient numbers were first reported in 2008-09. In 2011-12 when a patient is recorded with '0' grams for a primary diagnosis of 'DO Issue', these patients have been excluded from the total patient count. Also, these patients are not receiving product funded under the national blood arrangements. Previous reporting years included these patients. These numbers are small.

Patients with multiple diagnoses

Individual patients may have more than one diagnosis over time. In these cases, a patient may be counted more than once in the data in this report (ie the patient will be counted in the totals for each diagnosis).

Age and Weight

The STARS data has age and weight data recorded at treatment dates (first reported in 2009-10). This data will change over time. Year of birth is calculated from age data and applied that to all of the patient's treatments. Age data is based on the patient age at 1 January each year. Weight data is not recorded for all patients in STARS.

Criteria Chapters

Diagnoses and indications captured prior to the implementation of the *Criteria* were mapped to ensure that they were meaningfully represented, however information from previous years may not be directly comparable from 2008-09 forward. There is a small variance between disciplines by year due to mapping methodology (Table 5).

Treatments not included in the IVIg data

Treatments for the primary diagnosis often involve providing other clinically appropriate treatments and these are not counted in this report.

Trends in Issues of IVIg 2003 to 2012

A total of 3,271,309 grams were issued nationally in 2011-12, an increase of 320,938 grams over 2010-11. Of this total, approximately 22% was imported product.

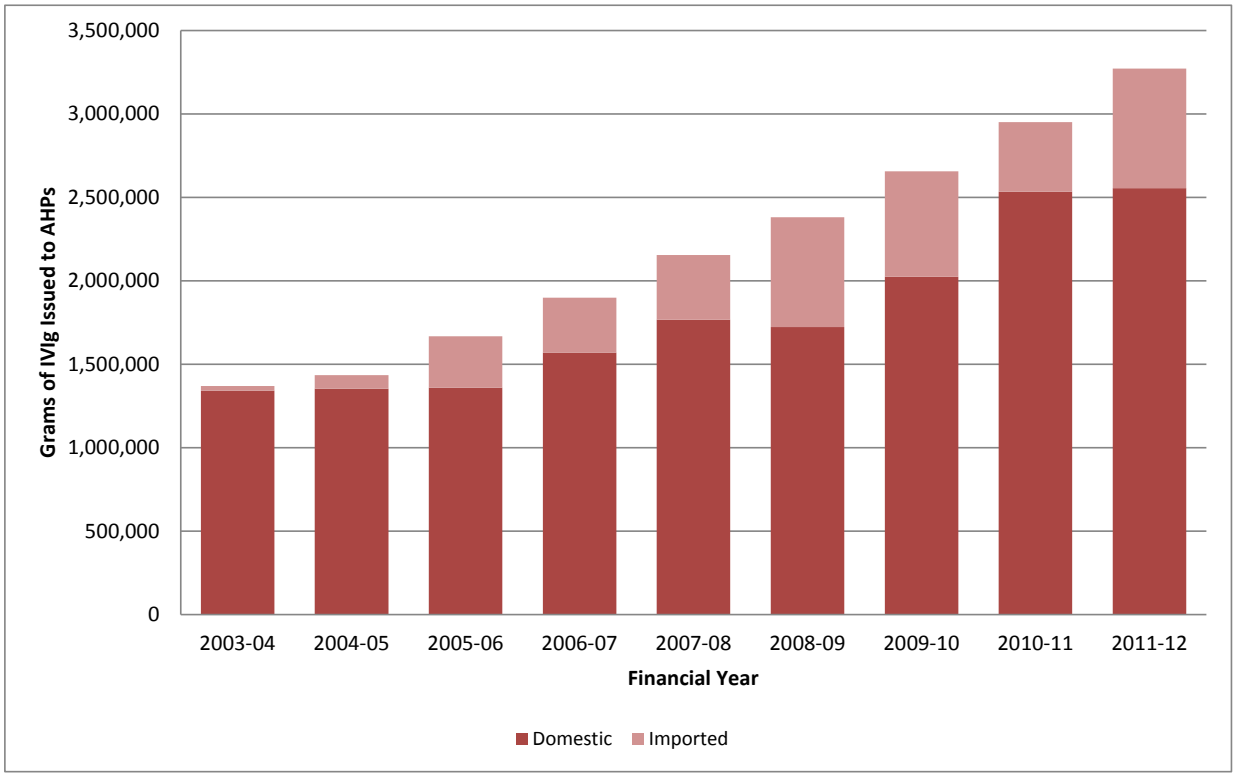

Figure 1 IVIg grams issued nationally 2003-04 to 2011-12 (IDMS)

	2004-05	2005-06	2006-07	2007-08	2008-09	2009-10	2010-11	2011-12
Growth from previous year	8.5%	14.2%	13.9%	13.4%	10.6%	11.6%	11.1%	10.9%
Average growth from 2003-04	8.5%	11.3%	12.2%	12.5%	12.1%	12.0%	11.9%	11.8%

Table 1 Growth in total IVIg issues from 2003-04 (IDMS)

Table 2 shows issues of total IVIg and growth presented by grams per 1000 head of population, with the rate growing from 121.1 grams per 1000 head of population in 2009-10 to 145.6 grams in 2011-12. The increase in grams per 1000 head of population continues to be higher than population growth of 1.4%[1].

[1] Australian Bureau of Statistics Catalogue No. 3101.0 Australian Demographic Statistics, Dec 2011

It is likely that some of the growth in per capita terms of IVIg use relates to the ageing of the Australian population and the strong correlation between age and conditions that are treated with IVIg.

The Australian Bureau of Statistics 3201.0 - Population by Age and Sex, Australian States and Territories, June 2010 notes that 'in the 12 months to 30 June 2010, the number of people aged 65 years and over in Australia increased by 94,800 people, representing a 3.3% increase. The proportion of the population aged 65 years and over increased from 11.1% to 13.5% between 30 June 1990 and 30 June 2010.

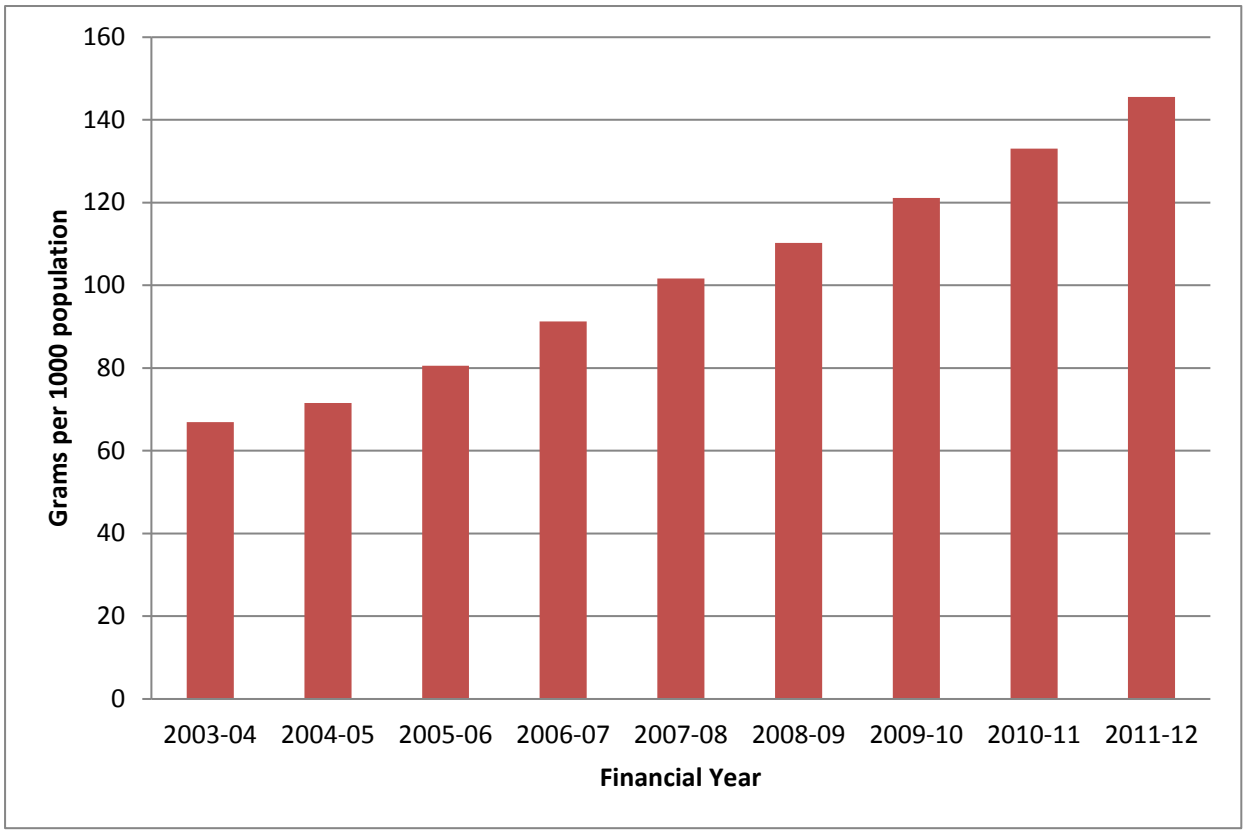

Figure 2 Grams of IVIg issued per 1000 population nationally (IDMS)

	2003-04	2004-05	2005-06	2006-07	2007-08	2008-09	2009-10	2010-11	2011-12
Total grams per 1000 population	66.8	71.6	80.5	91.1	101.7	110.3	121.1	133.0	145.6
Increase by year		7.1%	12.5%	13.1%	11.6%	8.5%	9.8%	9.8%	9.4%

Table 2 Grams of IVIg issued per 1000 population nationally and percentage change from previous year (IDMS)

Trends in Costs 2003 to 2012

Figure 3 shows the cost of providing IVIg under the national blood arrangements over time. Total finished product cost in 2011-12 was $204.4 million, an increase of $19.4 million over 2010-11. This excludes the separate cost of Australian plasma for fractionation to make domestically produced IVIg.

On average IVIg finished product costs have grown around 14% while average demand growth was 11.5% since 2003-04. The NBA has over the past eight years achieved savings on prices for both imported and domestic IVIg as part of contract negotiations compared to the previous growth and contracts

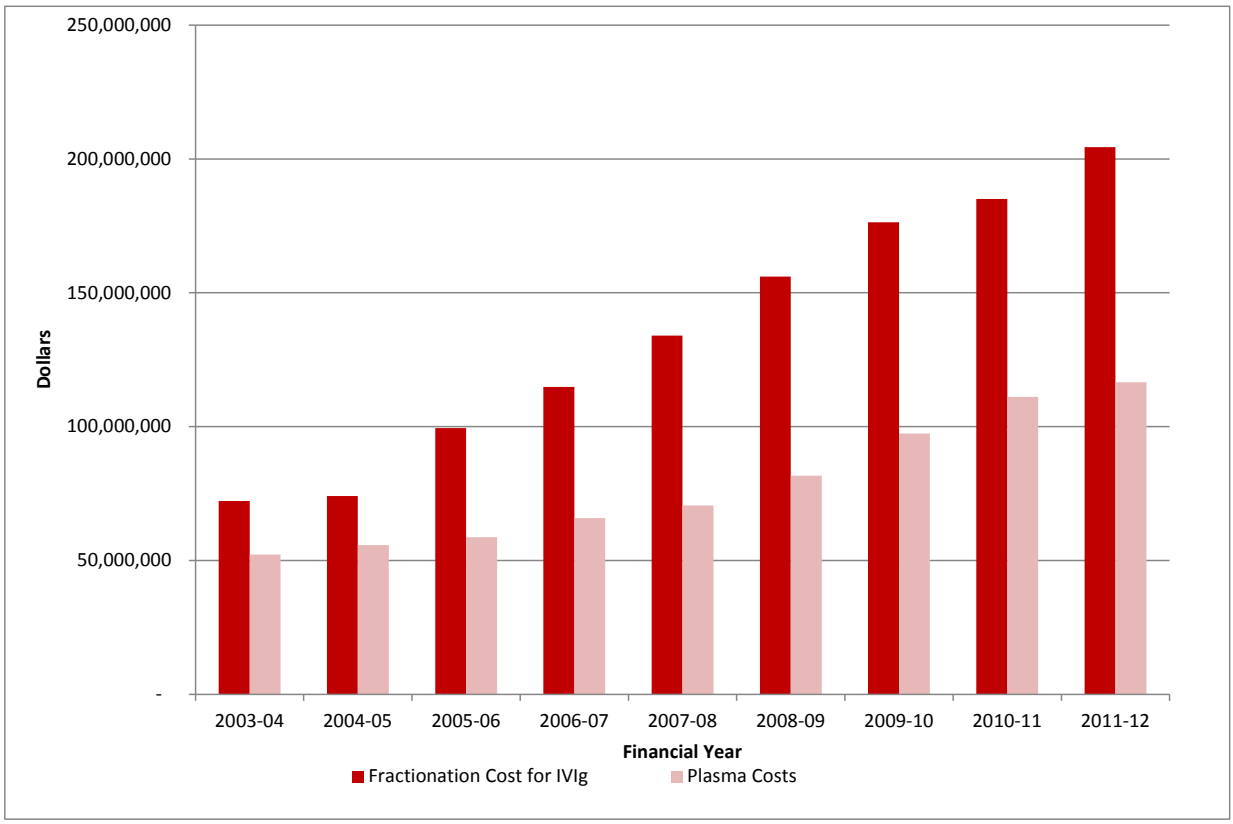

Figure 3 Costs for IVIg from 2003 to 2012 (NBA National Supply Plan & Budget)

Note: The cost of the recall of Octagam in 2011-12 is not included in Figure 4.

PLASMA FOR FRACTIONATION

The Blood Service collected 502 tonnes of plasma for fractionation in 2011-12 and 95% of this was used to produce domestic IVIg (Intragam P) and the remaining 5% was used for other hyperimmune products. Under the national blood arrangements the cost of plasma is paid for as a separate line item to the finished product cost and is allocated between states and territories based on their use of domestic immunoglobulin products.

SHARE OF TOTAL BLOOD PRODUCT BUDGET

Figure 4 illustrates the proportional cost of finished IVIg products within the National Supply Plan and Budget under the national blood arrangements. On this basis IVIg is the third largest budget contributor and represents nearly 22% of the total budget for blood and blood products.

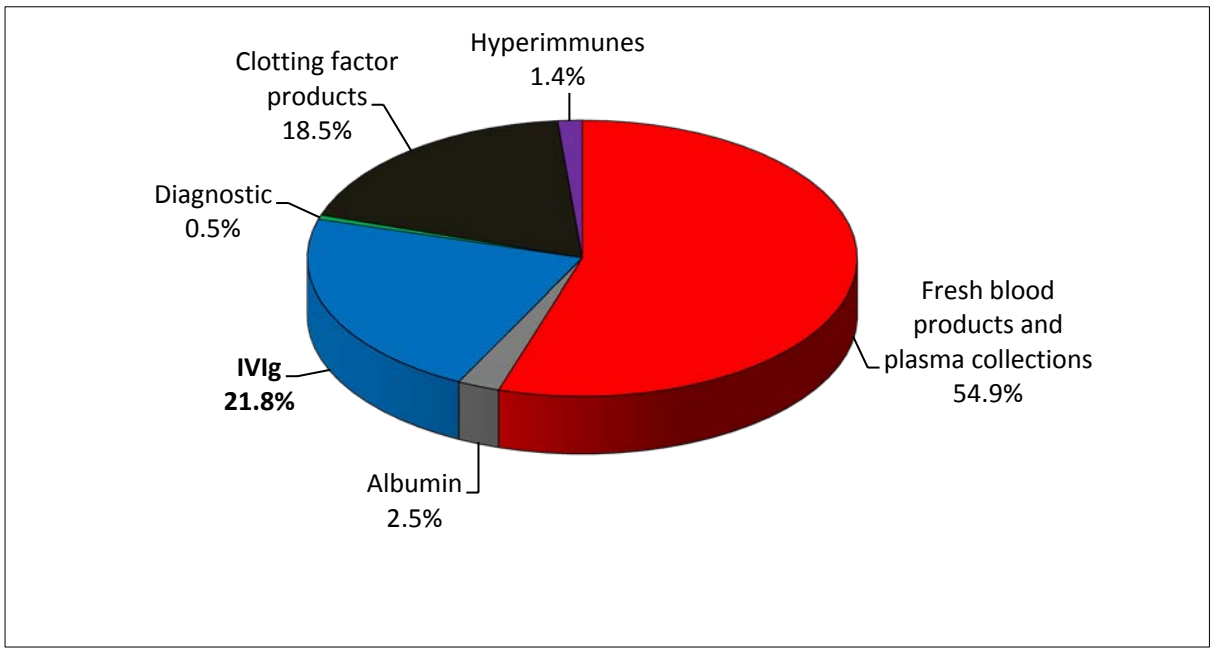

Figure 4 **Share of total expense 2011-12 (IDMS)**

Trends in Use

Since the introduction of the *Criteria*, IVIg data is often summarised by reference to the chapter of *the Criteria* which relates to the control of various conditions. The chapters described in *the Criteria* are:

- chapter 5, conditions for which IVIg has an established therapeutic role
- chapter 6, conditions for which IVIg has an emerging therapeutic role
- chapter 7, conditions for which IVIg has application in exceptional circumstances only
- chapter 8, conditions for which IVIg use is not indicated

USE BY CHAPTER

Table 3 and Table 4 outline the volume of IVIg grams issued per chapter. Pre 2008, data has been mapped to the current chapters and therefore may not be directly comparable. The highest amount of IVIg issued is for indications within Chapter 5, those for which IVIg has an established therapeutic role.

Chapter	2004-05	2005-06	2006-07	2007-08	2008-09	2009-10	2010-11	2011-12
Chapter 5	1,005,594	1,172,728	1,363,847	1,625,246	1,990,586	2,212,914	2,505,332	2,724,809
Chapter 6	402,416	400,682	368,458	417,939	345,176	371,832	397,231	444,605
Chapter 7	17,820	19,518	33,970	45,130	47,275	61,924	76,033	101,287
Chapter 8	13,110	16,259	15,351	8,888	3,326	2,550	2,574	1,909
Direct Orders				280		243	215	321
Other	43,056	47,730	76,426	37,743				

Table 3 IVIg grams issued by chapters in the criteria (STARS)

Chapter	2004-05	2005-06	2006-07	2007-08	2008-09	2009-10	2010-11	2011-12
Chapter 5	68%	71%	73%	76%	83%	84%	84%	83%
Chapter 6	27%	24%	20%	20%	14%	14%	13%	14%
Chapter 7	1%	1%	2%	2%	2%	2%	3%	3%
Chapter 8	1%	1%	1%	0%	0%	0%	0%	0%
Direct Orders	0%	0%	0%	0%	0%	0%	0%	0%
Other	3%	3%	4%	2%	0%	0%	0%	0%

Table 4 IVIg grams issued as a % of the total by criteria chapters (STARS)

USE BY DISCIPLINE

In 2011-12, in line with previous years, volumes of IVIg issued were greatest for the disciplines of neurology, haematology and immunology.

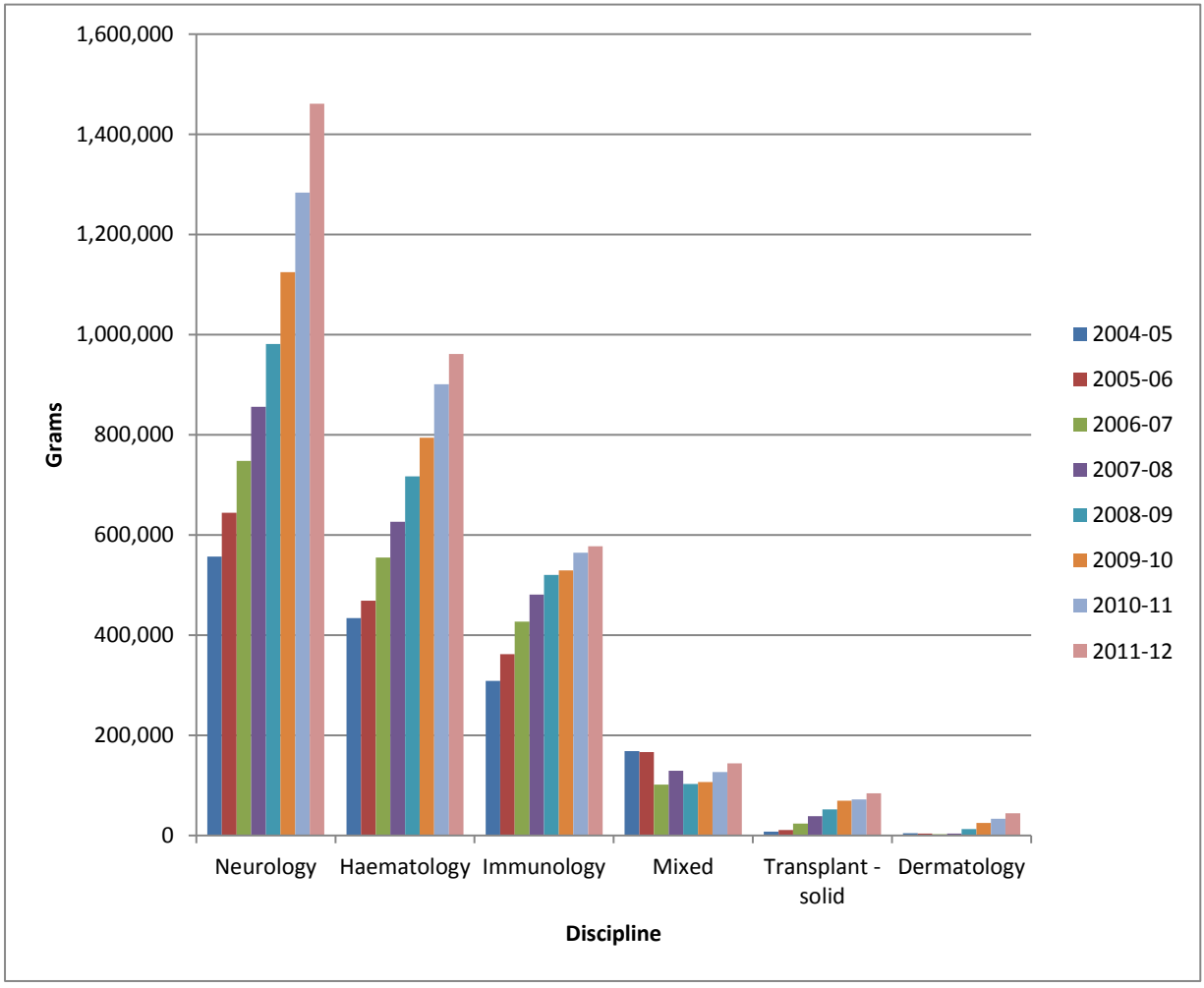

Figure 5 IVIg grams issued by discipline since 2004-05 (STARS)

Discipline	2004-05	2005-06	2006-07	2007-08	2008-09	2009-10	2010-11	2011-12
Neurology	556,974	644,329	748,109	855,874	981,372	1,124,604	1,283,190	1,460,622
Haematology	434,237	469,082	554,711	626,294	716,767	794,098	900,826	961,299
Immunology	308,999	361,821	426,837	481,401	520,264	529,132	564,752	577,559
Mixed	168,898	166,959	101,698	129,079	102,937	106,884	126,931	144,331
Transplant - solid	8,031	10,793	23,788	38,524	51,940	69,561	72,149	84,512
Dermatology	4,857	3,933	2,909	3,774	13,083	24,943	33,324	44,288

Table 5 IVIg grams issued by discipline by year (STARS)

USE PER 1000 POPULATION

The figure below presents national and state and territory, IVIg issues per 1000 population for the last eight years. Tasmania (TAS), Queensland (QLD), New South Wales (NSW) and the Australian Capital Territory (ACT) continue to have issues per 1000 population above the national rate, while the other states and territories are below the national rate. It should be noted that rates for the smaller population states and territories must be viewed with some caution. Western Australia (WA) and the Northern Territory (NT) have remained reasonably stable in terms of the issues per 1000 population, South Australia (SA) has had significant variability and all other states and territories have seen a continued strong increase in the issues per 1000 population. Patients who have moved from one state and territory to another may be reported in each state or territory where they received treatment.

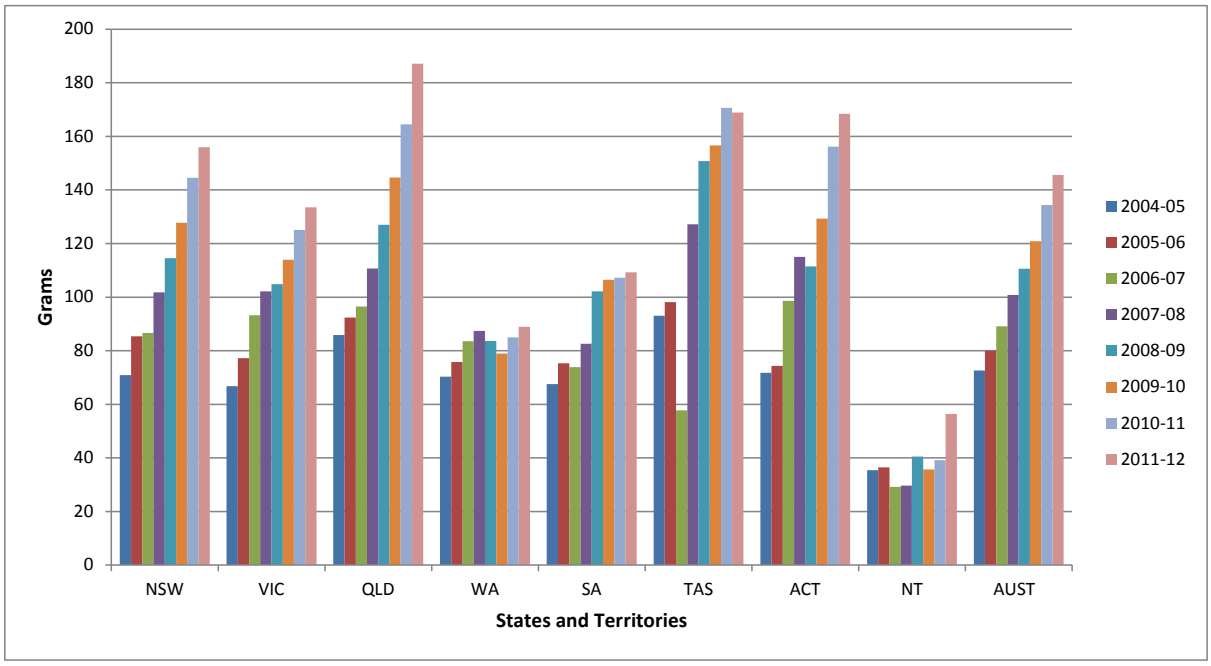

Figure 6 **IVIg grams issued per 1000 population by state and territory since 2004-05 (STARS)**

USE BY DISEASE GROUPS

The Blood Service is required to collect information on diagnosis and indication for use as part of the authorisation of product requests. The top ten uses of IVIg by disease groups have changed over time and are presented in Figure 7.

Acquired hypogammaglobulinaemia secondary to haematological malignancies is the disease group for which the greatest per cent of IVIg was issued in 2011-12 (21.2%) closely followed by Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) (20.7%). Primary Immunodeficiency diseases accounted for 14.6% of total IVIg use.

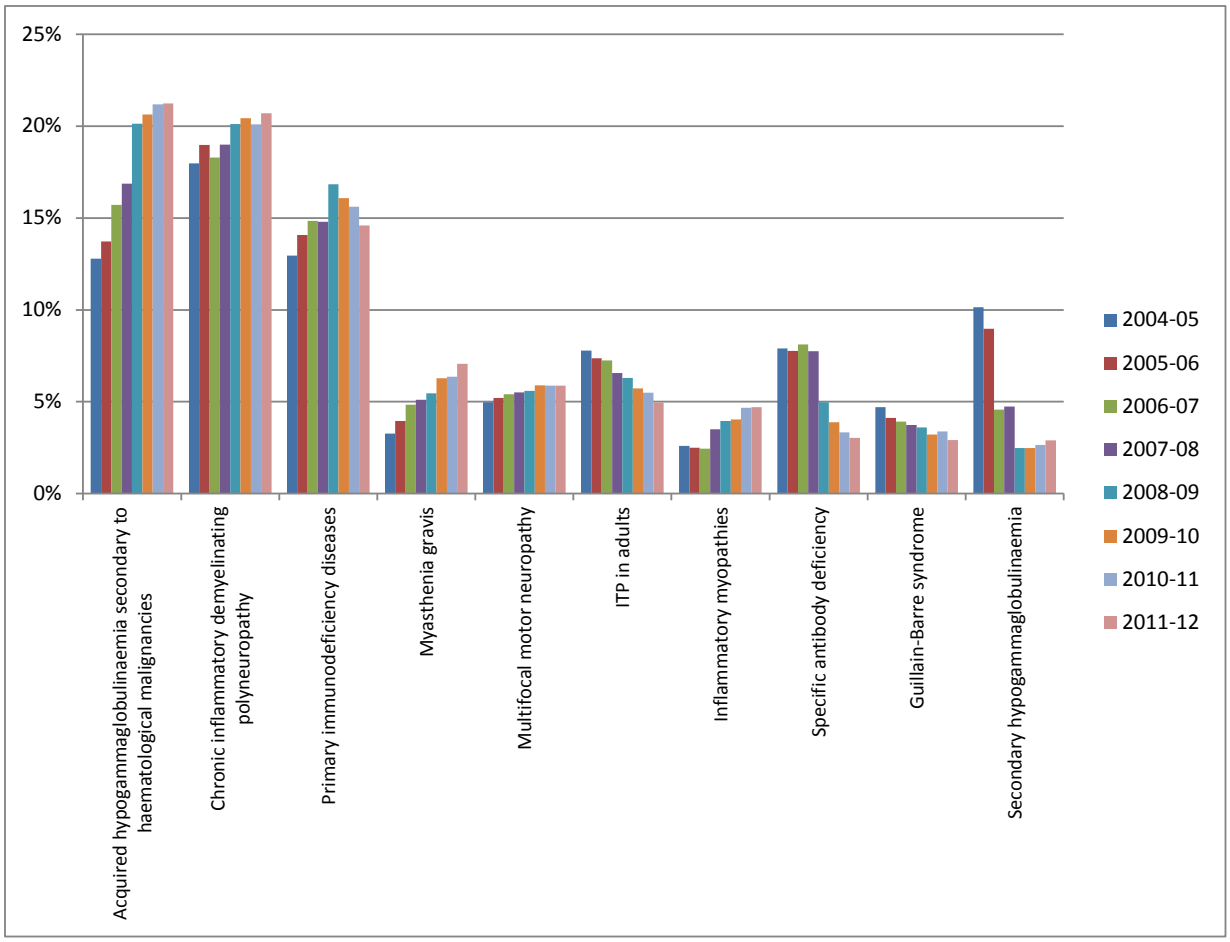

Figure 7 **Top 10 uses of IVIg by disease group (STARS)**

2011-12 in review

RECONCILIATION

A reconciliation of STARS and IDMS data indicates small variances at a national level. Greater variation is seen within the data for individual states and territories. In some cases these differences can be explained by product being ordered and recorded in STARS the month prior to product actually being issued.

State	2004-05	2005-06	2006-07	2007-08	2008-09	2009-10	2010-11	2011-12
NSW	3.6%	-0.1%	-0.5%	0.0%	-1.0%	-1.3%	1.3%	-0.9%
VIC	-6.1%	-4.3%	-2.9%	0.4%	2.2%	1.7%	2.5%	4.0%
QLD	11.7%	6.7%	-4.3%	-3.8%	-1.2%	-0.6%	-1.1%	-1.5%
SA	0.6%	-5.4%	4.6%	3.3%	5.1%	-1.0%	5.1%	-0.7%
WA	-4.4%	-2.3%	-1.2%	-0.1%	-0.6%	0.0%	-0.4%	1.0%
TAS	-1.8%	1.3%	-11.7%	-2.2%	2.6%	0.6%	2.3%	1.0%
NT	-6.4%	-4.0%	-7.9%	-5.5%	-13.7%	-5.2%	-1.7%	-2.0%
ACT	-3.7%	-17.0%	-1.1%	-9.2%	4.5%	3.0%	-1.0%	-7.0%
TOTAL	**1.5%**	**-0.6%**	**-2.1%**	**-0.8%**	**0.3%**	**-0.2%**	**1.1%**	**0.0%**

Table 6 Reconciliation of STARS issues data to IDMS

In 2011-12, STARS recorded 3,272,930 grams of IVIg while the NBA's IDMS recorded 3,271,309 grams of IVIg issued nationally. Of these 2,555,046 grams were domestic IVIg (78%) and 716,263 grams (22%) imported IVIg. A total of 12,127 patients were issued IVIg under the National Blood Arrangements for 101,388 patient episodes.

Year	No. of Patients	No. of Treatment Episodes	Total Grams Issued
2008-09	9,870	77,212	2,386,361
2009-10	10,537	85,299	2,649,462
2010-11	11,492	93,893	2,981,385
2011-12	12,127	101,388	3,272,930

Table 7 Annual numbers of patients, treatments and grams recorded in STARS

TOTAL ISSUES AND EXPENDITURE

Table 8 shows the total grams of IVIg issued in 2011-12 by state and territory, while Figure 8 depicts the state and territory issues in a graphical form.

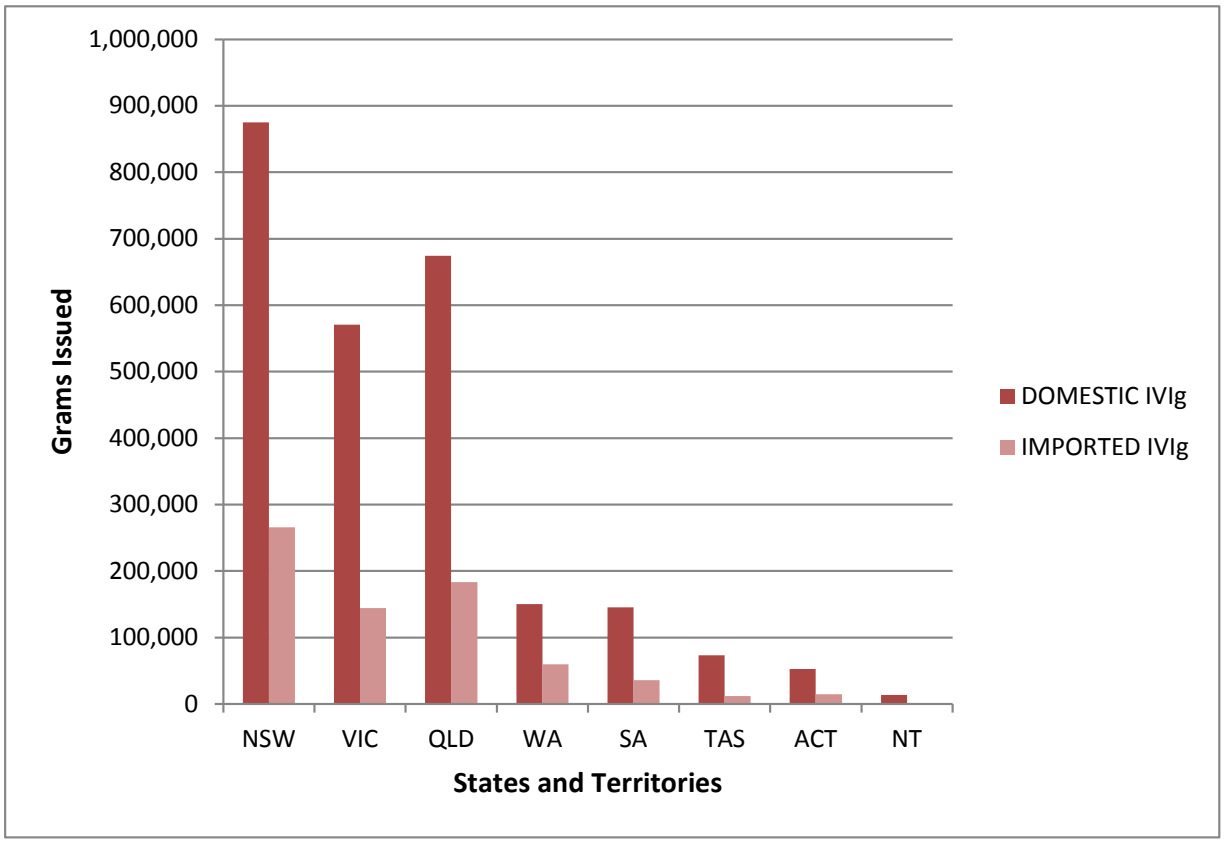

Figure 8 IVIg grams issued by state and territory 2011-12 (IDMS)

		NSW	VIC	QLD	WA	SA	TAS	ACT	NT
2011-12	**IMPORTED IVIg**	265,995	144,283	183,435	59,900	35,775	12,137	14,708	30
	DOMESTIC IVIg	874,995	570,969	674,277	150,294	145,134	73,491	52,446	13,440
	Proportion of Imported	23.3%	20.2%	21.4%	28.5%	19.8%	14.2%	21.9%	0.2%

Table 8 IVIg grams issued by state and territory 2011-12 (IDMS)

State	Sum of Grams	Proportion of total issues	Proportion of Australian Population	Grams per 1000 population
NSW	1,140,990	34.9%	32.2%	157.4
VIC	715,253	21.9%	24.8%	128.3
QLD	857,712	26.2%	20.1%	190.1
WA	210,194	6.4%	10.6%	88.0
SA	180,909	5.5%	7.3%	110.0
TAS	85,629	2.6%	2.3%	167.3
ACT	67,154	2.1%	1.6%	181.1
NT	13,470	0.4%	1.0%	57.6
Total	**3,271,309**	**100.0%**	**100.0%**	**145.5**

Table 9 IVIg issued as recorded in IDMS for 2011-12 (IDMS)

In 2011-12 the national average IVIg grams issued per 1000 population was 145.5. Different patient populations within the states and territories impact these figures. Factors affecting the number of patients include the age distribution, cross border treatment and the incidence of particular diseases. For example, SA and TAS have older population proportions than other states and territories, however, their rates of use of IVIg are different. Smaller patient numbers may mean that specific patient needs may impact these figures. ACT may also be affected by providing services to NSW residents (cross border issues).

Year	NSW	VIC	QLD	WA	SA	TAS	ACT	NT
2006-07	12.8%	19.8%	17.7%	10.3%	-10.8%	29.9%	12.4%	-15.9%
2007-08	18.2%	7.6%	16.4%	6.3%	14.1%	4.6%	29.2%	1.4%
2008-09	15.2%	2.8%	14.4%	-0.5%	22.9%	14.3%	-14.1%	53.9%
2009-10	13.4%	11.0%	15.2%	-3.9%	11.8%	6.9%	19.9%	-18.0%
2010-11	11.2%	10.2%	15.6%	10.4%	-4.5%	7.9%	28.3%	6.6%
2011-12	11.5%	6.6%	16.0%	6.2%	8.5%	0.7%	16.9%	46.7%

Table 10 Annual growth of IVIg by state and territory from previous year (NBA National Supply Plan and Budget)

Despite the introduction and promulgation of the *Criteria* in 2008, setting uniform access criteria for IVIg, the growth in its use varies significantly across states and territories. This, together with the strong growth in total use of IVIg, has generated interest in a better understanding of the clinical demand, treatment, and management arrangements for IVIg in each state and territory.

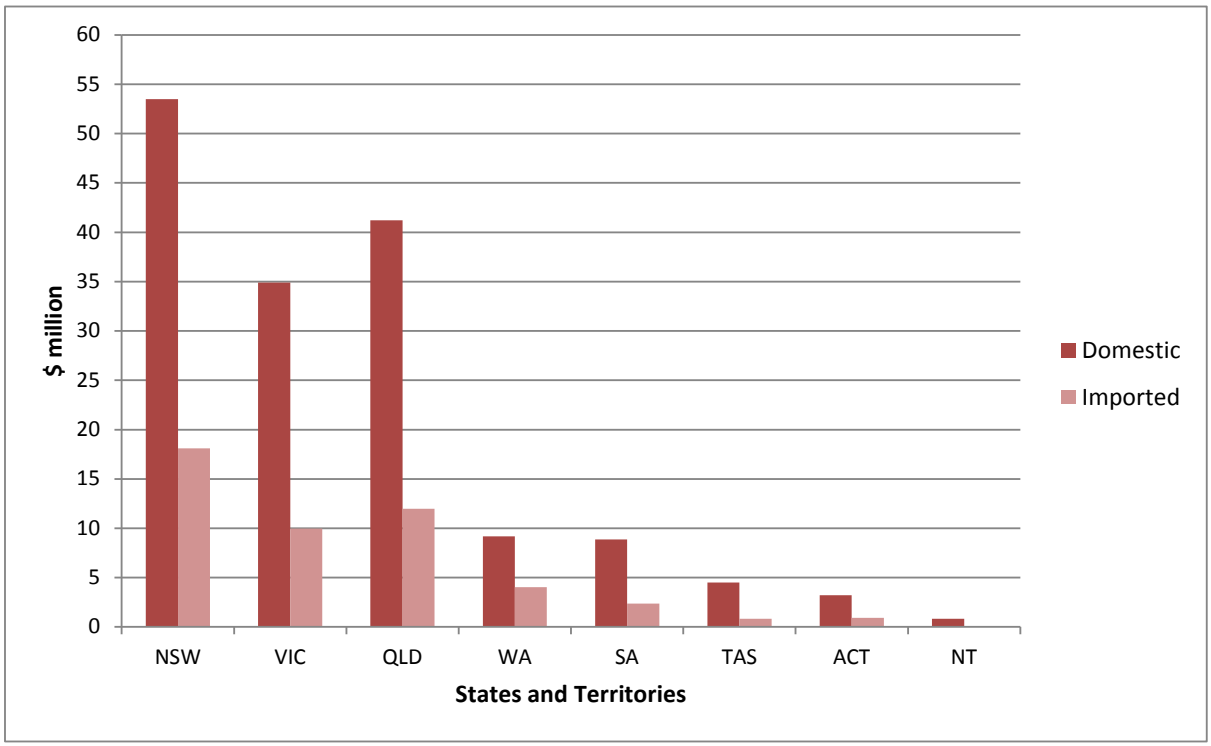

Figure 9 2011-12 costs of IVIg by state and territory (NBA National Supply Plan & Budget)

In response to the issues mentioned previously, in March 2011, a joint meeting of the Clinical, Technical and Ethical Principal Committee (CTEPC) and the Jurisdictional Blood Committee (JBC) agreed to a review of the authorisation process and clinical governance framework for IVIg as a priority task. In March and September 2013 the JBC endorsed the recommendations of the review and approved an implementation program over three years. Information on the review findings and the work program to implement its recommendations can be found at clinical governance review[2].

[2] http://www.blood.gov.au/ivig-clinical-governance-review

IVIG ISSUED BY TOP 10 PRIMARY DIAGNOSIS BY STATE AND TERRITORY

The top 10 uses of IVIg by primary diagnoses by state and territory and nationally for 2011-12 are presented in Figure 10. The top 10 diagnoses differ between states and territories. As shown in Figure 10 nationally, CIDP (20.7%), Common Variable Immunodeficiency Disease (CVID) (12.3%), Chronic Lymphocytic Leukaemia (CLL) (7.4%) and Myasthenia Gravis (7.1%) were the indications for which the greatest proportion of IVIg was issued in 2011-12.

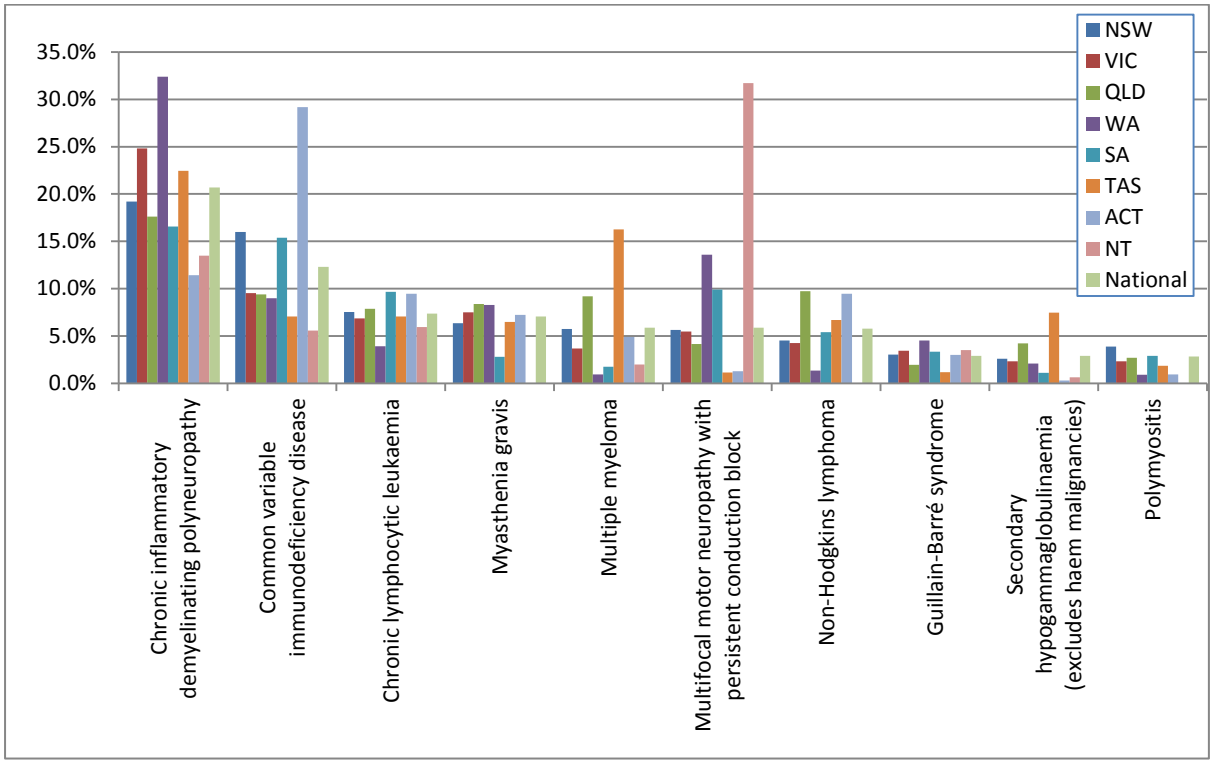

Figure 10 **Proportion of IVIg issued by top 10 diagnoses by state and territory (STARS)**

IVIG GRAMS ISSUED PER 1000 POPULATION BY STATE AND TERRITORY

The grams issued per 1000 population for each indication varies between state and territory and complete data for primary diagnosis for each state and territory can be found at **Appendix C**. The more notable differences in average dose per patient by disease group for Chapter 5 are shown in Table 11.

Chapter	Disease Group	NSW	VIC	QLD	WA	SA	TAS	ACT	NT	AUST
Chapter 5	Acquired hypogammaglobulinaemia secondary to haematological malignancies	32.5	22.6	53.6	6.2	19.2	53.7	42.5	6.7	30.9
	CIDP	30.0	33.1	32.9	28.8	18.1	37.9	19.2	7.6	30.1
	Primary immunodeficiency diseases	27.6	18.2	21.0	10.2	18.5	12.6	49.8	5.4	21.2
	Myasthenia gravis	9.9	10.0	15.7	7.4	3.1	11.0	12.2	0.0	10.3
	Multifocal motor neuropathy	8.8	7.3	7.7	12.1	10.8	1.9	2.2	17.9	8.5
	ITP in adults	7.4	6.1	8.8	4.8	9.5	7.1	6.8	7.6	7.2
	Inflammatory myopathies	9.5	5.8	6.9	1.6	6.4	11.4	4.1	0.0	6.8
Chapter 5	**Total**	**132.1**	**109.5**	**153.7**	**75.6**	**89.8**	**139.2**	**142.3**	**47.7**	**121.2**
Chapter 6	Specific antibody deficiency	6.4	2.9	3.2	4.4	3.9	5.2	8.0	0.9	4.4
	Secondary hypogammaglobulinaemia	4.0	3.1	7.9	1.8	1.2	12.6	0.5	0.4	4.2
	Kidney transplantation	1.6	7.4	2.7	0.9	1.5	3.6	0.2	2.7	3.2
	HSCT (for prevention of GvHD in high risk Allogeneic HSCT)	0.3	1.9	7.4	0.0	3.4	0.0	0.0	0.0	2.3
Chapter 6	**Total**	**18.5**	**20.4**	**28.0**	**10.4**	**15.3**	**23.3**	**19.7**	**7.5**	**19.8**
Chapter 7	**Total**	**5.4**	**3.4**	**5.5**	**2.6**	**4.0**	**6.4**	**6.4**	**1.2**	**4.5**
Grand Total	**Grand Total**	**155.9**	**133.5**	**187.2**	**88.9**	**109.3**	**168.9**	**168.4**	**56.4**	**145.6**

Table 11 IVIg grams issued per 1000 population by diagnosis and state and territory (STARS)

Note: Caution should be used when interpreting these figures for the smaller states and territories.

Understanding the differences in the amount of IVIg issued per 1000 population between states and territories for the more common indications would be beneficial. For example, the amount of IVIg

issued per 1000 head of population for CIDP varies between 8 grams and 38 grams, with the national average being 30 grams.

PATIENT COUNTS

Excluding IVIg issued under direct orders, a total of 12,127 unique patients were issued IVIg nationally during 2011-12 and there were 101,388 patient episodes. Patient numbers by quarter are shown in Table 12. Note these are numbers of the unique patients for whom IVIg was issued in the quarter. A particular patient may be treated in a number of quarters and will be counted for each treatment. It is also possible that a particular patient may appear in more than one state and territory due to patient movement between states and territories.

Year	Qtr	NSW	VIC	QLD	WA	SA	TAS	ACT	NT	AUST
2008-09	Q1	2,216	1,296	1,448	402	331	145	105	13	5,956
	Q2	2,255	1,327	1,466	399	364	151	105	19	6,086
	Q3	2,261	1,313	1,470	357	362	170	99	17	6,049
	Q4	2,383	1,356	1,544	373	395	177	98	31	6,357
2009-10	Q1	2,447	1,377	1,652	385	400	184	112	24	6,581
	Q2	2,499	1,388	1,670	357	440	177	109	20	6,660
	Q3	2,556	1,394	1,682	354	395	183	102	15	6,681
	Q4	2,607	1,460	1,755	373	413	189	121	22	6,940
2010-11	Q1	2,707	1,506	1,839	376	420	197	144	22	7,211
	Q2	2,784	1,545	1,887	395	394	205	132	21	7,363
	Q3	2,761	1,544	1,888	379	397	214	130	15	7,328
	Q4	2,800	1,628	1,947	385	419	200	142	23	7,544
2011-12	Q1	2,933	1,665	2,047	408	421	199	142	27	7,842
	Q2	2,976	1,631	2,115	413	430	206	137	22	7,930
	Q3	2,956	1,594	2,150	403	431	203	150	23	7,910
	Q4	2,961	1,633	2,215	405	459	202	154	29	8,058

Table 12 Number of unique patients IVIg issued by state and territory by quarter (STARS)

From Table 12, between June 2011 and June 2012 there was an increase of 7.8% unique patients.

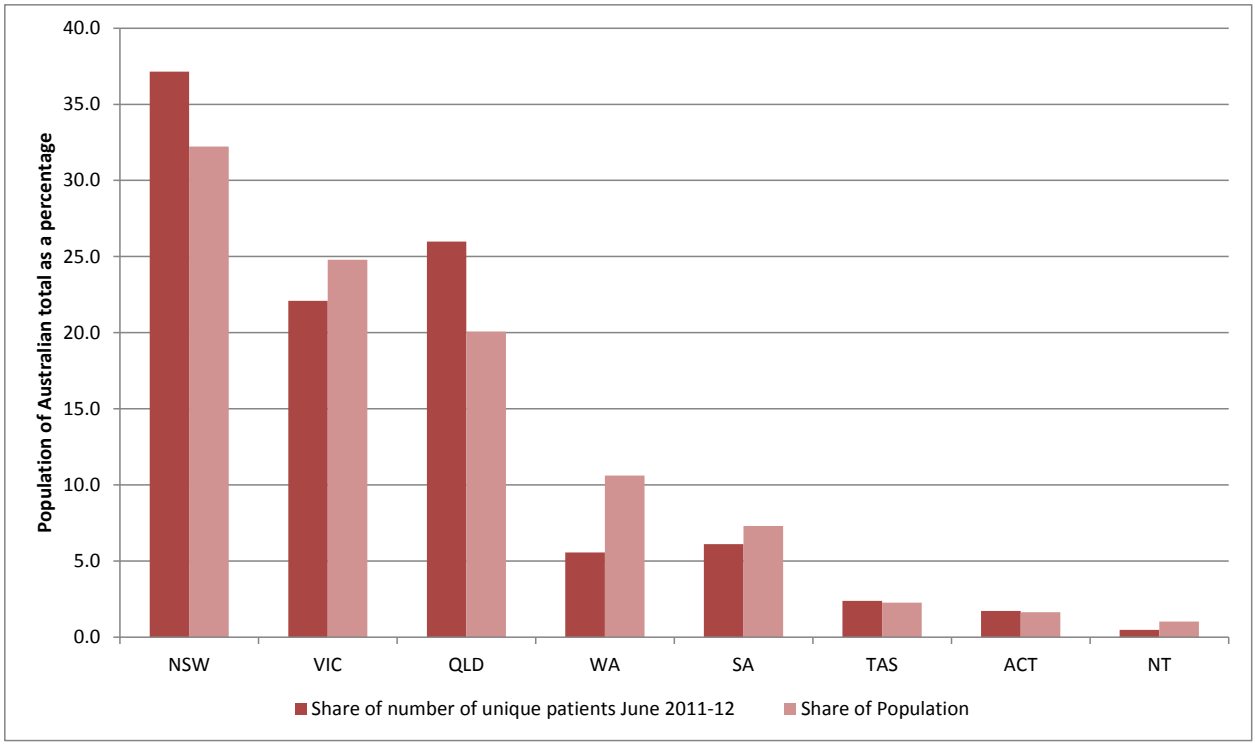

Figure 11 **State and territory share of patients receiving IVIg compared with the share of population in June quarter 2012 (STARS, ABS)**

Figure 11 shows the state and territory share of patient numbers and compares them with the states and territories population share for 2011-12.

Figure 12 shows the variability between the states and territories in the numbers of unique patients and Figure 13 shows the number of treatment episodes. Moreover, the figures show that most states and territories have strong growth in numbers and treatment episodes underpinning their growth in use of IVIg.

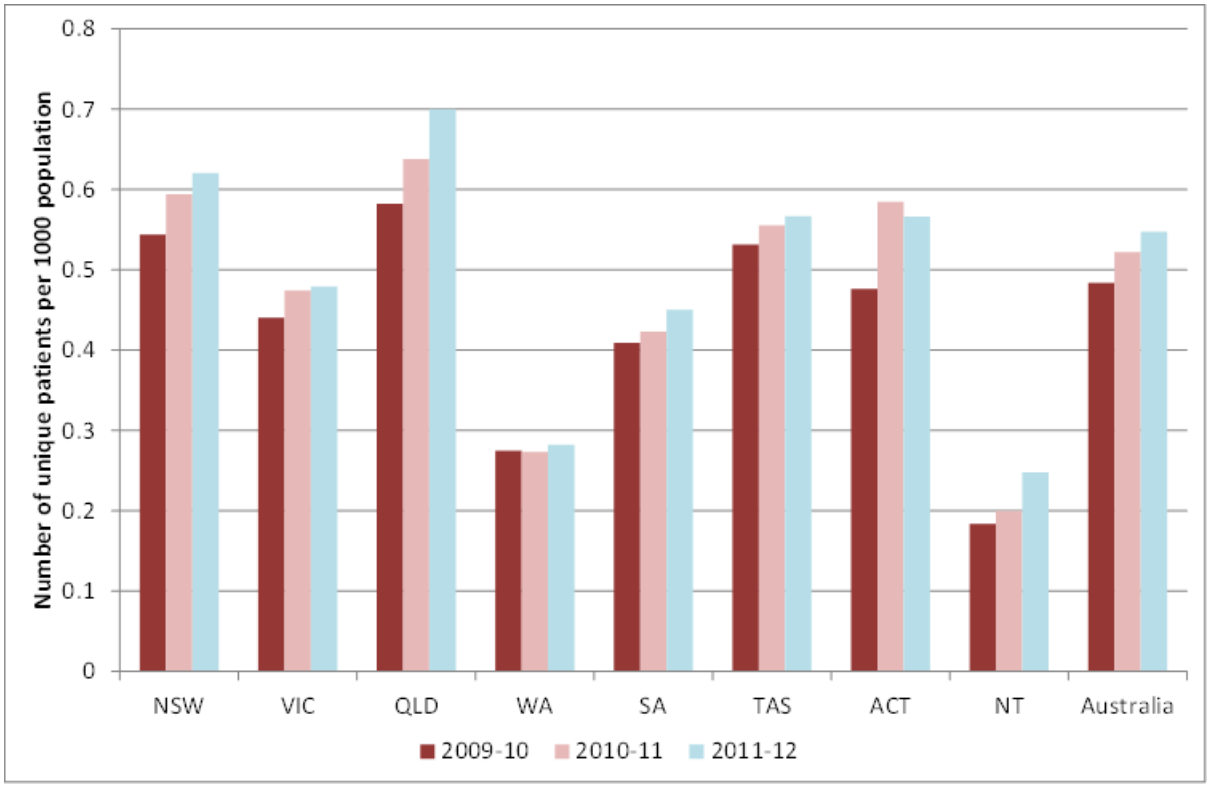

Figure 12 Numbers of unique patients by state and territory 2009 to 2012 (STARS)

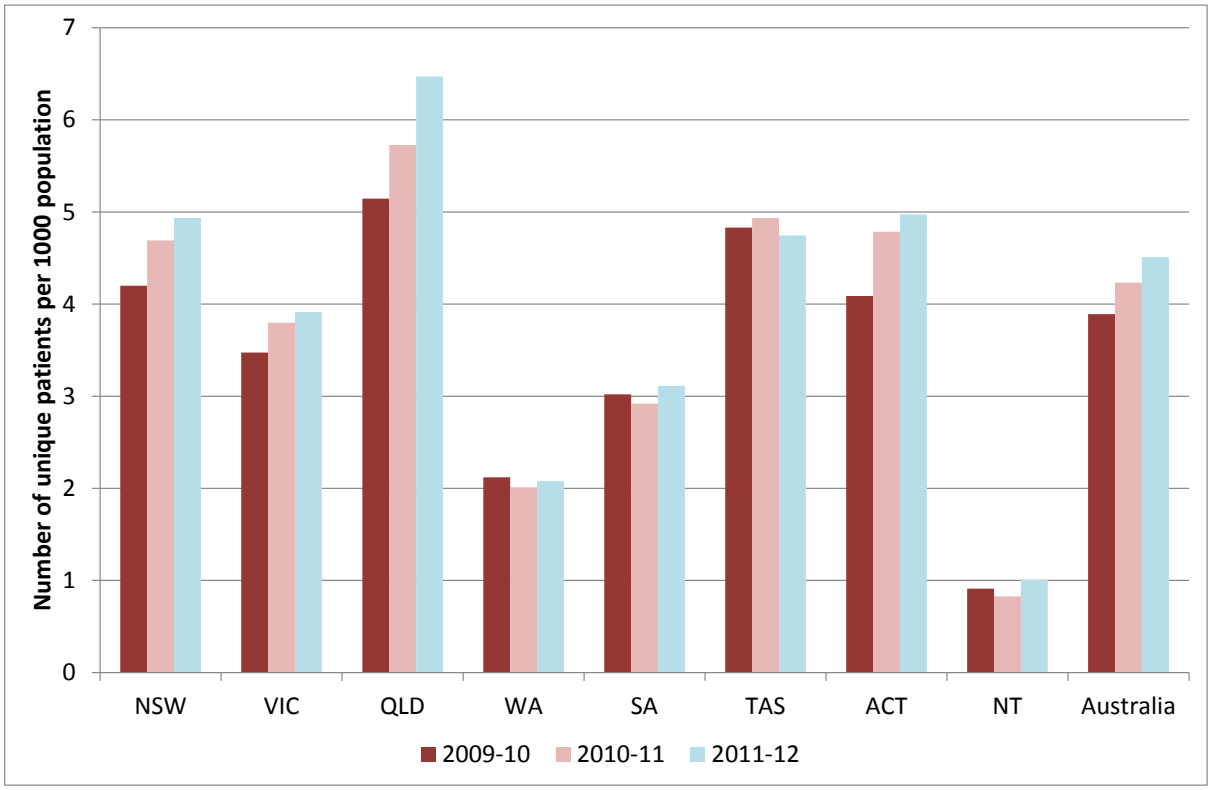

Figure 13 Treatment episodes per 1000 population by state and territory 2009 to 2012 (STARS)

VARIABILITY BETWEEN STATES AND TERRITORIES

Variability between states and territories in the way IVIg is used may by measured in a number of ways. Table 13 shows the average grams issued to patients with selected indications. **Appendix C** shows the grams IVIg per 1000 population the grams issued per episode for the different indications is shown at **Appendix D**. Clearly, any of these measures for the states and territories with smaller populations should be viewed with caution. Table 13 presents the differences for twenty disease groups using the largest amounts of IVIg. In general, such variance in average grams per patient between the national average and state and territory averages warrants further consideration. In particular, it would be informative to understand the reasons for the variation in the dose issued for some of the more common indications such as CIDP and multifocal motor neuropathy. For example, in some Chapter 6 disease groups, there is more than a two-fold variation in dose issued per patient between the large patient population states and territories.

Disease Group	NSW	VIC	QLD	WA	SA	TAS	ACT	NT	AUST
Chapter 5									
Acquired hypogammaglobulinaemia secondary to haematological malignancies	191.0	211.9	229.3	162.0	194.2	229.0	258.2	175.0	208.8
CIDP	363.2	496.6	385.2	694.7	408.1	647.0	419.5	355.8	428.8
Guillain-Barre syndrome	184.4	173.1	155.7	159.9	153.5	145.3	187.9	155.0	170.6
Inflammatory myopathies	315.3	396.3	356.2	243.2	329.4	486.9	377.0		341.3
ITP in adults	162.0	131.5	152.9	157.7	145.3	125.1	195.3	127.1	149.5
Kawasaki disease	40.7	40.6	35.4	45.6	32.4	30.0	29.0	42.0	39.3
Multifocal motor neuropathy	469.5	542.0	416.1	995.6	937.5	327.0	266.7	1046.3	544.2
Myasthenia gravis	327.2	396.0	391.5	487.6	264.8	330.0	451.9		370.9
Primary immunodeficiency diseases	288.4	310.1	285.7	313.2	265.1	306.0	329.4	159.4	292.7
Stiff person syndrome	449.4	598.6	879.0		145.5	648.0		63.0	587.1
Chapter 6									
Autoimmune haemolytic anaemia	135.5	120.9	163.9	88.9	234.8	81.0	150.0		139.1
Foeto-maternal /neonatal alloimmune thrombocytopenia	454.5	273.6	349.7	137.3	242.0				282.2
HSCT (for prevention of GvHD in high risk Allogeneic HSCT)	86.2	276.8	279.4	28.5	250.5				252.5
IgM para-proteinaemic neuropathy	251.9	256.8	296.4	814.0	198.8				299.0
Kidney transplantation	129.1	260.9	285.5	191.5	116.7	366.0	60.0	212.0	217.9
Pemphigoid	607.6	725.0	849.0	211.7	85.0		1251.0		640.0
Pemphigus	701.6	435.0	857.5	237.0	750.0		628.5		617.7
Secondary hypogammaglobulinaemia	168.2	218.0	215.6	105.0	167.7	358.2	59.0	84.0	192.7
Specific antibody deficiency	279.4	289.4	204.7	225.8	306.6	378.4	297.6	102.0	263.3
Toxic shock syndrome	117.4	137.5	122.3	86.8	110.0	200.0	72.0	224.0	128.5

Table 13 Average grams IVIg issued per patient by disease group and state and territory 2011-12 (STARS)

ISSUED AND REPORTED AS 'CRITERIA NOT MET'

The Blood Service was asked to indicate circumstances where IVIg was issued to patients who did not meet the *Criteria* in Chapters 5, 6 or 7. IVIg can be issued in life threatening situations prior to diagnosis or in situations where the clarification process[3] has not published a 'resolution' and the JBC has decided to allow continued access to IVIg until such time as a resolution is published.

Table 14 lists the requests that did not meet the *Criteria* but for which product was issued by the Blood Service.

	2008-09			2009-10			2010-11			2011-12		
	Patients	Episodes	Issued Grams	Patients	Episodes	Issued Grams	Patients	Episodes	Issued Grams	Patients	Episodes	Issued Grams
Criteria Not Met	852	2,325	69,094	60	139	4,569	37	43	1,644	22	31	1,519
Indefinite	1	2	48									
DO Advised				13	0	0	20	0	0	16	0	0
DO Issued	2	1	140	7	9	378	5	6	215	8	11	321
Pending	28	94	2,603	9	17	474	39	85	2,996	15	32	1,252
Single	1	1	27	1	13	507	1	1	30	1	5	165
Not approved	39	0	0	61	0	0	65	0	0	19		
Total	**923**	**2,423**	**71,912**	**151**	**178**	**5,928**	**167**	**135**	**4,885**	**81**	**79**	**3,256**

Table 14 Issues of IVIg under the National Blood Arrangements which did not meet the criteria **(STARS)**

The application of the *Criteria* means that the number of patients receiving IVIg who do not meet the *Criteria* has fallen from 852 in 2008-09 to 22 patients in 2011-12.

[3] As part of the process to implement the new *Criteria*, the NBA established a clarification process in November 2008. A consultation group was consulted on specific queries that arose in relation to interpretation of the *Criteria*. Consideration of the queries and comments resulted in some amendments to specific indications in the *Criteria*.

Demographics of IVIg patients

This section provides demographic information on patients to whom IVIg was issued based on the entries in the STARS database between the September Quarter 2008 and the June Quarter 2012. For this analysis it is assumed that the patient identifications (IDs) recorded in STARS data are unique, sequential and increasing over time.

Table 15 shows basic numbers.

	Count
Total unique patient IDs	25,375
Total unique patient IDs with some weight data	19,965
Total unique patient IDs with an age recorded	21,317
Total unique patient IDs with a weight change	3,392
Total unique patient IDs with more than one state and territory	518
Total unique patient IDs with two state and territories	473
Total unique patient IDs with three or more states and territories	36
Total unique patient IDs with more than one diagnosis	1,547
Total unique patient IDs with two diagnoses	1,322
Total unique patient IDs with three diagnoses	194
Total unique patient IDs with four diagnoses	26
Total unique patient IDs born 1920 or earlier	176

Table 15 Basic numbers (STARS)

Sep-09	Dec-09	Mar-10	Jun-10	Sep-10	Dec-10	Mar-11	Jun-11	Sep-11	Dec-11	Mar-12	Jun-12
1,369	1,267	975	921	1,403	1,127	1,233	1,210	1,444	1,268	1,153	1,096

Table 16 Additions to the database - number of patient IDs added in quarter (STARS)

Table 16 shows that the average number of new patients each quarter since September 2010 is over 1,000.

The STARS data has age and weight data recorded at treatment dates. This data will change over time. The year of birth is calculated from age data and applied that to all of the patient's treatments. The distribution of estimated birth years is shown in Figure 14 where it is compared with the age distribution of the Australian population from the ABS.

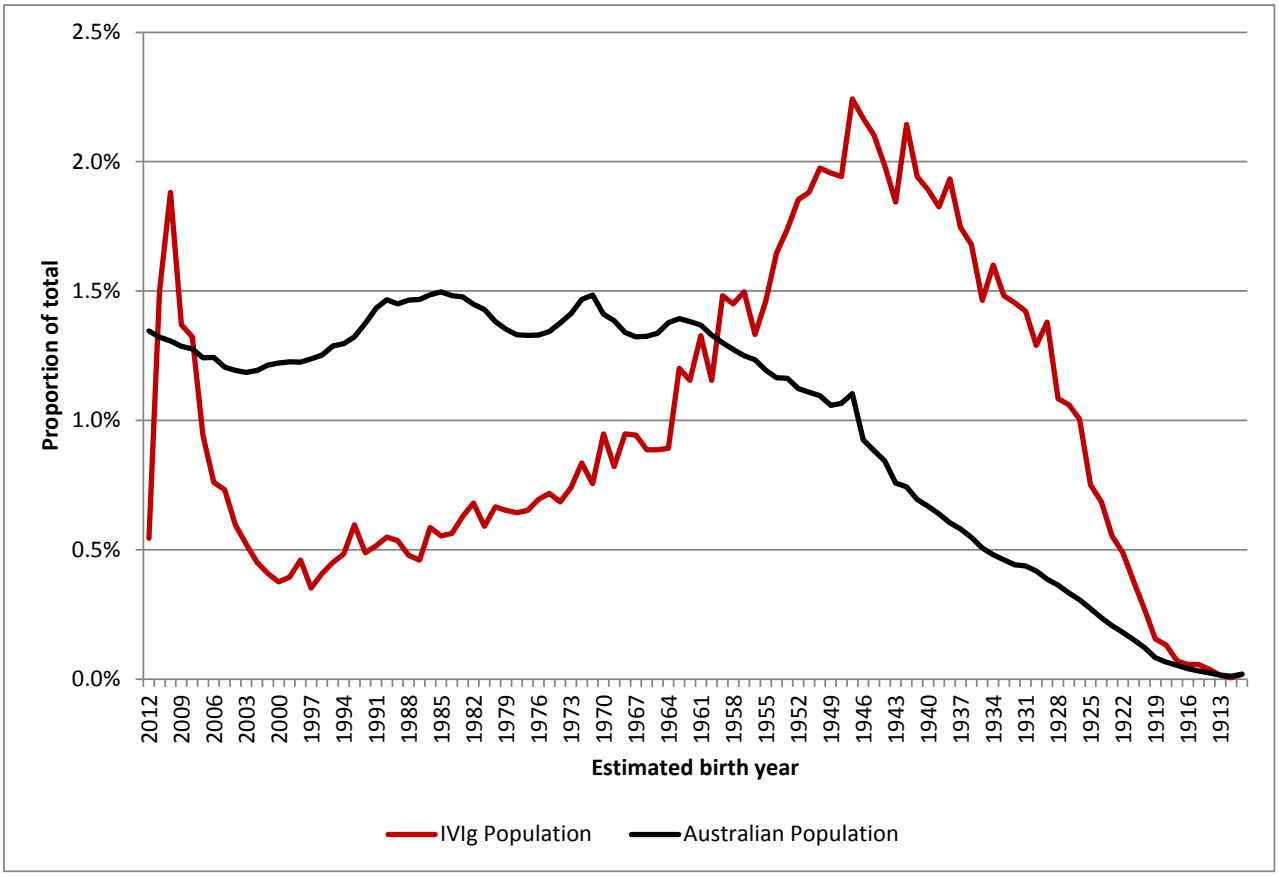

Figure 14 Proportion of IVIg patient IDs by estimated birth year (STARS, ABS)

Figure 14 shows that there is a spike of IVIg issued for the very young and those over 70 years. The median birth year of patients for whom IVIg is issued is 1951, compared to the median birth year for the Australian population, from the Australian Bureau of Statistics Series 3235.0, which is 1973[4] (ie. age 37.3) as at June 2011. This indicates that half the IVIg issued is for patients over 60.

The age profiles of the different states and territories are shown in Figure 15 and Table 17. It can be seen that the NT has a very young profile with a higher population in the early working age period. The ACT also has a higher population in the working years. SA and TAS have older populations and lower than average proportion in working ages.

	NSW	VIC	QLD	WA	SA	TAS	ACT	NT	AUS
Year	1950	1953	1950	1957	1952	1948	1956	1972	1951

Table 17 Median estimated year of birth for IVIg patients (STARS)

[4] Australian Bureau of Statistics Catalogue No. 3235.0 released 31 August 2012 – accessed at http://www.abs.gov.au/ausstats/abs@.nsf/Products/3235.0~2011~Main+Features~Main+Features?OpenDocument#PARALINK5 accessed on 01 July 2013

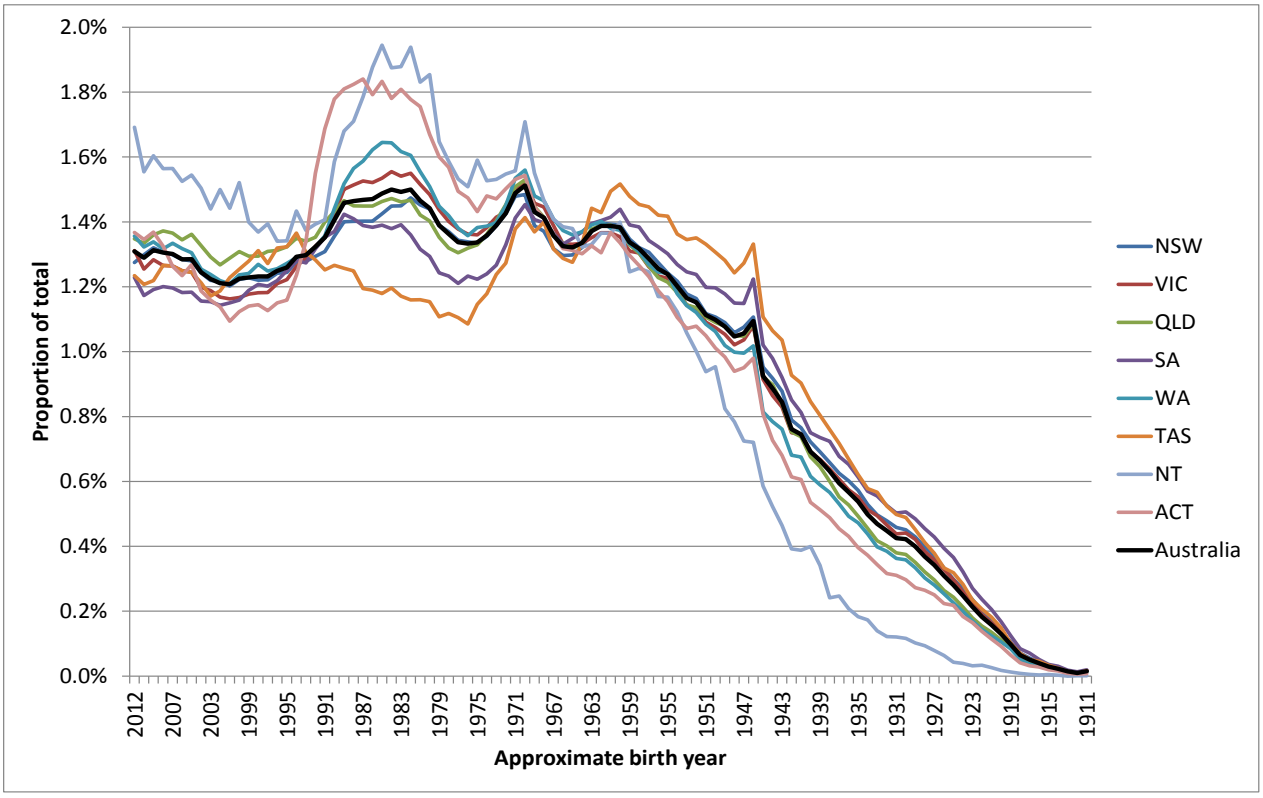

Figure 15 Proportion of population 2012 by approximate birth year (STARS)

Figure 16 shows the cumulative distribution of estimated birth years. States and territories with lines to the left of the national trend have generally younger age profiles than states and territories with lines to the right.

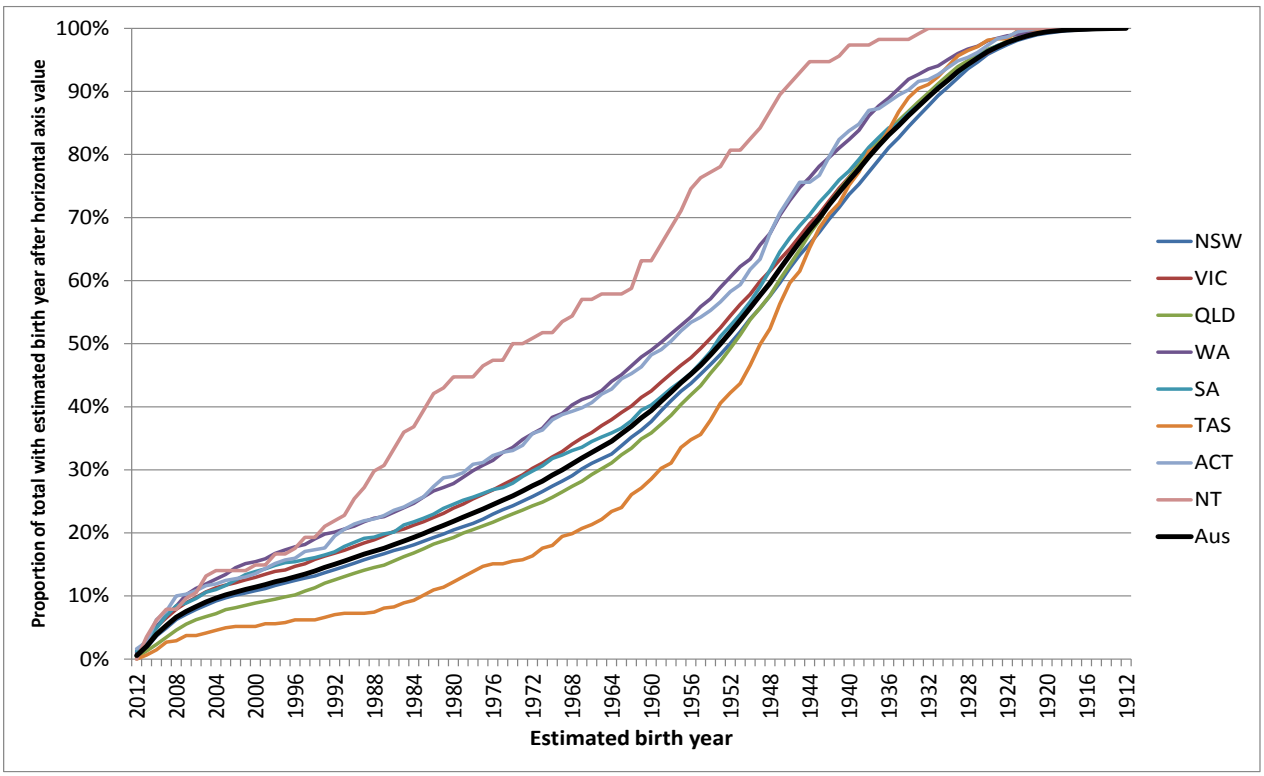

Figure 16 Cumulative distribution of estimated birth year of IVIg patients by state and territory (STARS)

Primary Diagnosis (Top 40)	Patients (not unique)	Number with age	% with age data	Median estimated birth year	Total grams over the four years 2008-12
CIDP	2,483	2,206	89%	1946	2,297,813
CVID	1,668	1,552	93%	1957	1,463,676
CLL	1,845	1,610	87%	1938	875,739
Myasthenia gravis	1,034	916	89%	1947	717,435
Multifocal motor neuropathy with persistent conduction block	560	504	90%	1952	657,202
Multiple myeloma	1,698	1,458	86%	1941	649,967
Non-Hodgkin lymphoma	1,313	1,182	90%	1944	565,714
Guillain-Barré syndrome	2,134	1,628	76%	1958	367,721
Secondary hypogammaglobulinaemia (excludes haem malignancies)	993	826	83%	1959	299,054
Polymyositis	413	363	88%	1949	292,253
ITP refractory	1,680	1,273	76%	1949	283,983
Other relevant haematological malignancies	1,114	899	81%	1957	261,504
IgG subclass deficiency existing patients only	335	255	76%	1949	249,297
ITP in specific circumstances (surgery, corticosteroids contraindicated, chronic ITP)	1,359	1,077	79%	1949	221,509
Kidney transplantation post-transplant	682	597	88%	1963	193,762
HSCT (for prevention of GvHD in high risk Allogeneic HSCT).	601	492	82%	1961	173,496
Specific antibody deficiency	675	267	40%	1956	171,131
Other primary immunodeficiency	307	199	65%	1960	150,925
X-linked agammaglobulinaemia	145	<5	<5	<5	121,309
Inclusion body myositis	162	139	86%	1938	104,498
Dermatomyositis	170	147	86%	1961	97,658
ITP with life-threatening haemorrhage	469	384	82%	1950	73,984
Stiff person syndrome	48	43	90%	1958	67,341
Foeto-maternal /neonatal alloimmune thrombocytopenia (Antenatal)	58	46	79%	1978	56,133
Autoimmune haemolytic anaemia	354	275	78%	1946	53,418
IgM para-proteinaemic neuropathy	85	71	84%	1937	44,689
Kawasaki disease	1,107	831	75%	2007	44,390

Primary Diagnosis (Top 40)	Patients (not unique)	Number with age	% with age data	Median estimated birth year	Total grams over the four years 2008-12
ITP in pregnancy	251	207	82%	1979	42,796
Potassium channel antibody-associated encephalopathy	118	110	93%	1962	36,843
Pemphigus vulgaris	42	41	98%	1958	35,795
Epilepsy (rare childhood cases)	64	58	91%	2002	32,990
Toxic Shock Syndrome (TSS) - streptococcal	250	192	77%	1967	32,445
Solid organ - lung	202	178	88%	1960	31,743
Paraneoplastic syndromes	128	111	87%	1953	29,337
Severe combined immunodeficiency	55	53	96%	1963	28,524
Kidney transplantation pre-transplant	257	194	75%	1961	28,429
Toxic epidermal necrolysis/Steven Johnson syndrome	201	159	79%	1970	27,010
ITP in children	485	368	76%	2006	24,752
Bullous pemphigoid	23	22	96%	1946	22,477
Acute disseminated encephalomyelitis	125	102	82%	1984	20,976

Table 18 Median estimated year of birth for IVIg patients for the top 40 primary diagnoses and grams for 2008 to 2012 (STARS)

Table 18 shows the median estimated year of birth for patients with the top 40 diagnoses who were issued IVIg. For a number of indications the proportion of patients with age data recorded is lower than for other indications.

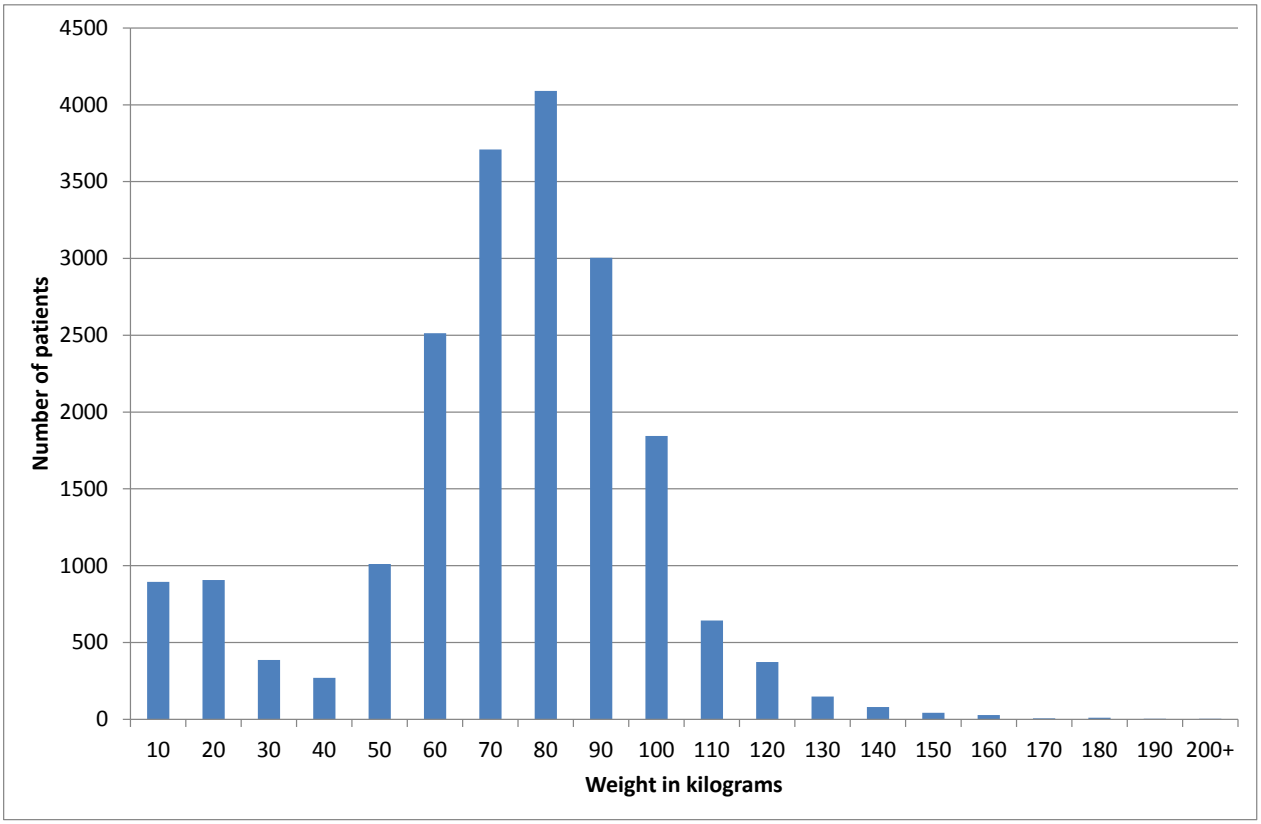

Figure 17 Distribution of reported weight of IVIg patients (STARS, ABS)

Although weight data is not recorded for all patients in STARS, Figure 17 shows the weight distribution of patients receiving IVIg where weight is recorded.

Figure 18 is a comparison with ABS survey data from 1995. As the ABS data is for adults only, IVIg patients with weight 20kg or less are not included in the distribution. Current ABS data reports on body mass index which is calculated from body weight and height.

The data in STARS did not include complete weight data so this is compared with older 1995 ABS data. The STARS data does not have gender so the average comparison is crude. IVIg is issued to patients based on weight and there is an association between increased age and weight, although average weights would appear to be slightly lower than the general Australian population.

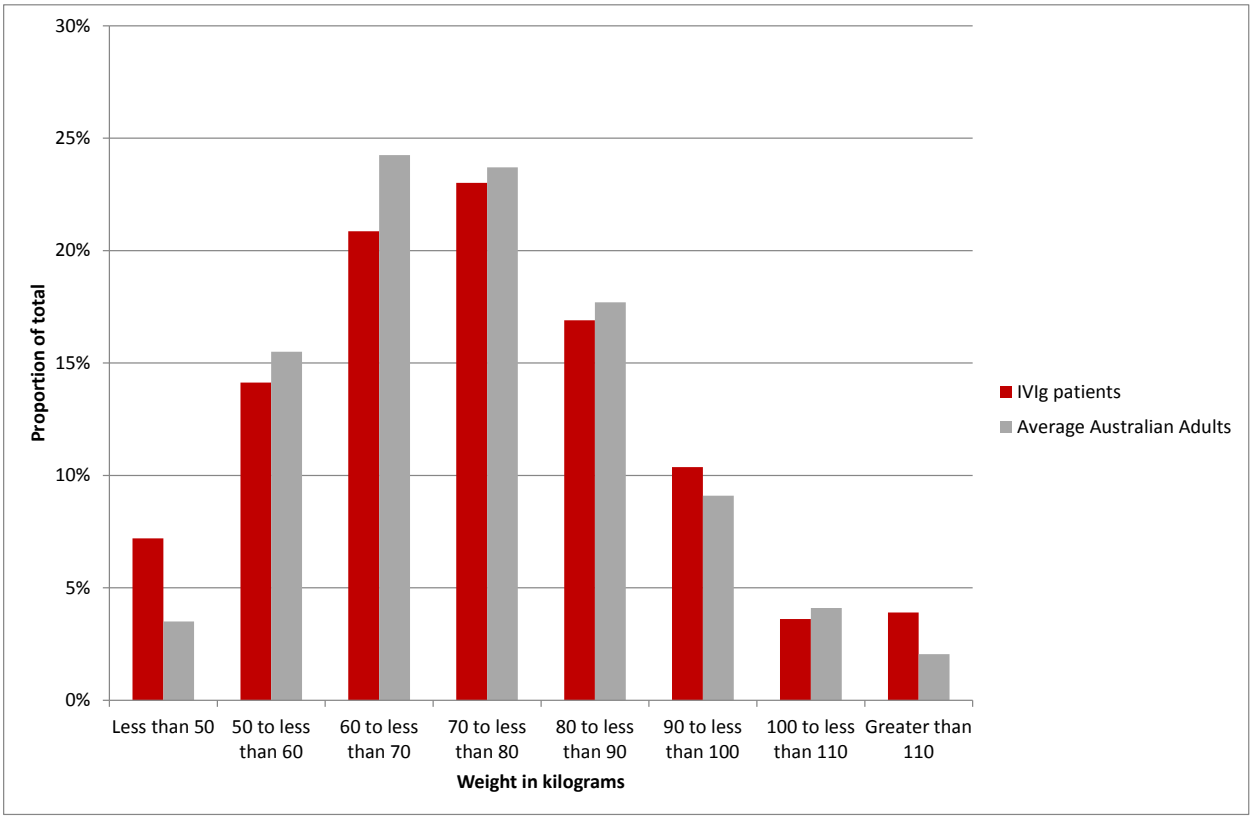

Figure 18 **The weight distribution of IVIg patients compared with adult Australia population (STARS, ABS)**

DOSING - NEW PATIENTS COMPARED WITH EXISTING PATIENTS FOR SELECTED DIAGNOSES

For all indications, understanding initial and maintenance dosing of IVIg assists with understanding clinical demand and informed decision making. A random selection of patients within the five indications using the greatest amount of IVIg was analysed to identify whether:

- there are clear differences in how new patients are dosed in relation to existing patients
- patient doses increase or decrease after initial dose
- the pattern of IVIg issued over time for patients with chronic conditions

Patients have been classified as new in a quarter if they appear for the first time in that quarter for a diagnosis. September quarter 2008 is the baseline.

Chronic inflammatory demyelinating polyneuropathy (CIDP)

The following series of charts (Figure 19, Figure 20, Figure 21 and Figure 22) show numbers of patients and amounts of IVIg for patients with CIDP. Figure 19 and Figure 20 show that the numbers of patients and total grams are increasing at a steady rate. The increase over the sixteen quarters is 54% for numbers of patients and 58% for total grams. In Figure 21 the grams per patient shows that the growth in total grams is driven mainly by the increase in numbers of patients. When the data is considered in terms of the amount per episode in Figure 22 the trend appears to be stable.

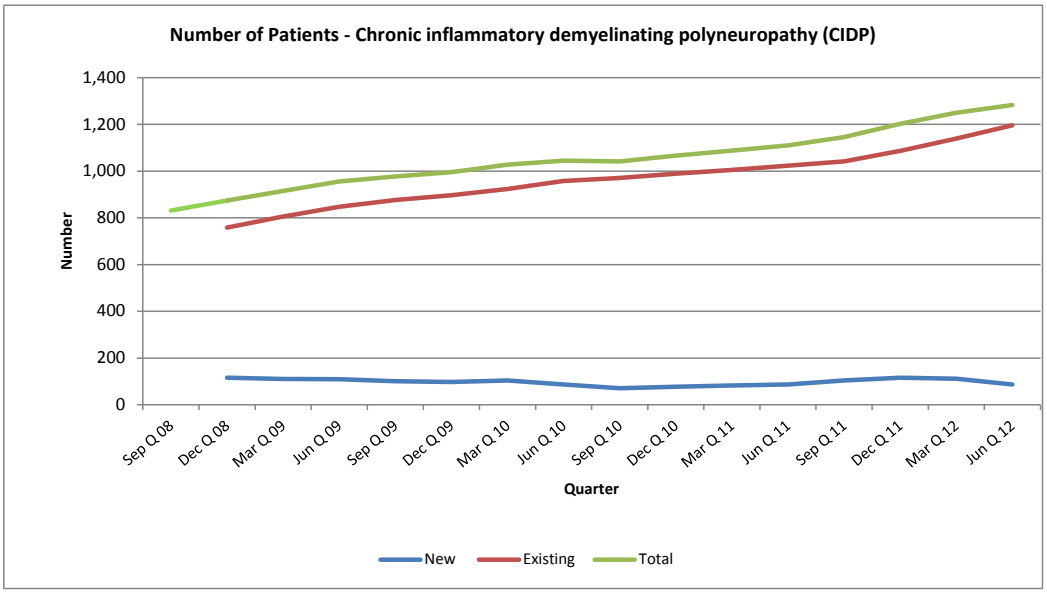

Figure 19 CIDP - new and existing number of patients (STARS)

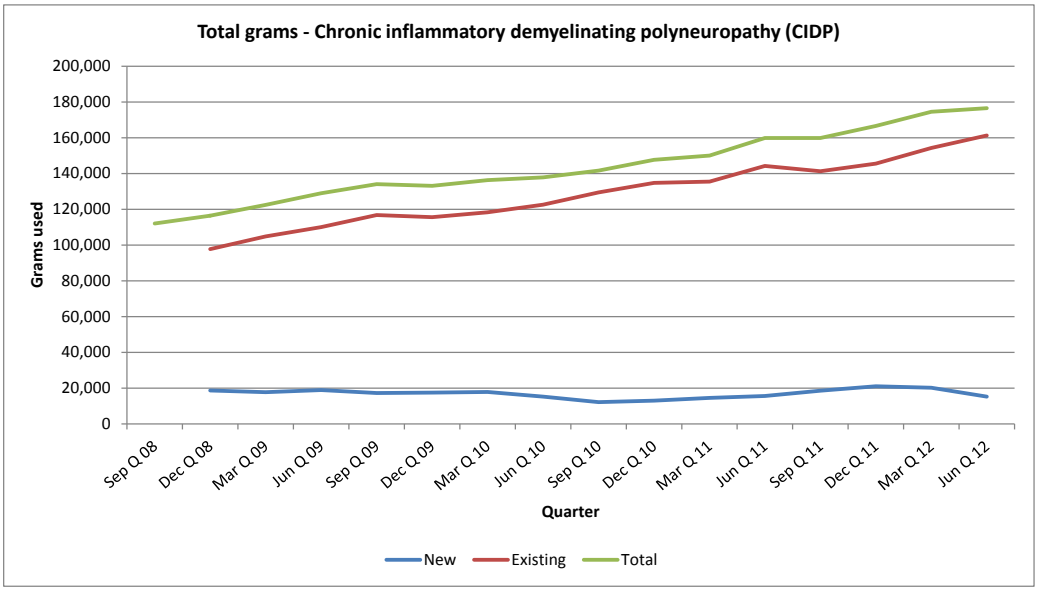

Figure 20 CIDP - new and existing total grams (STARS)

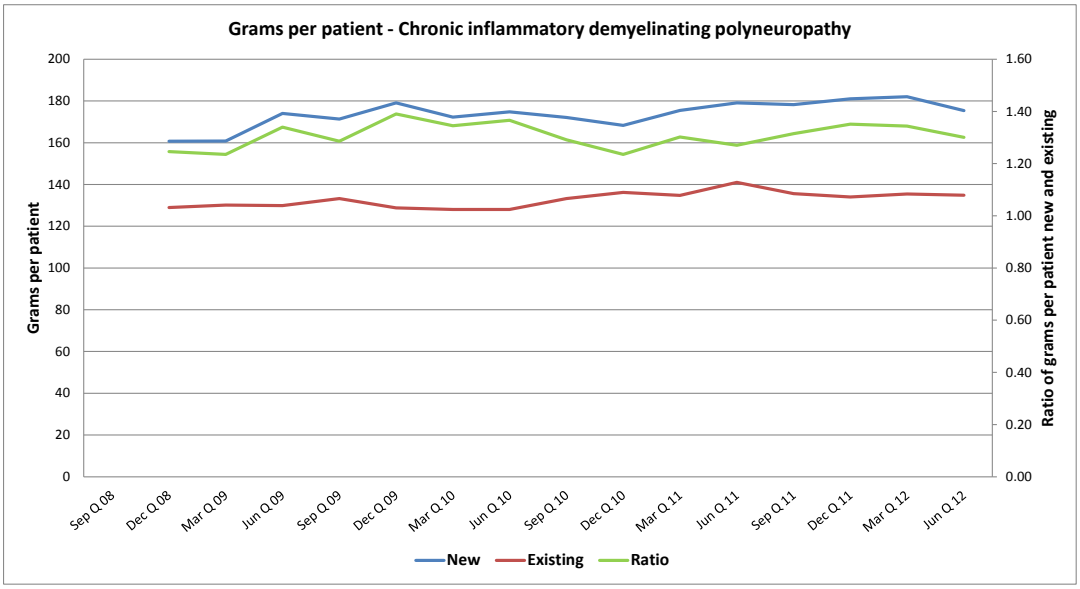

Figure 21 CIDP - new and existing grams per patient (STARS)

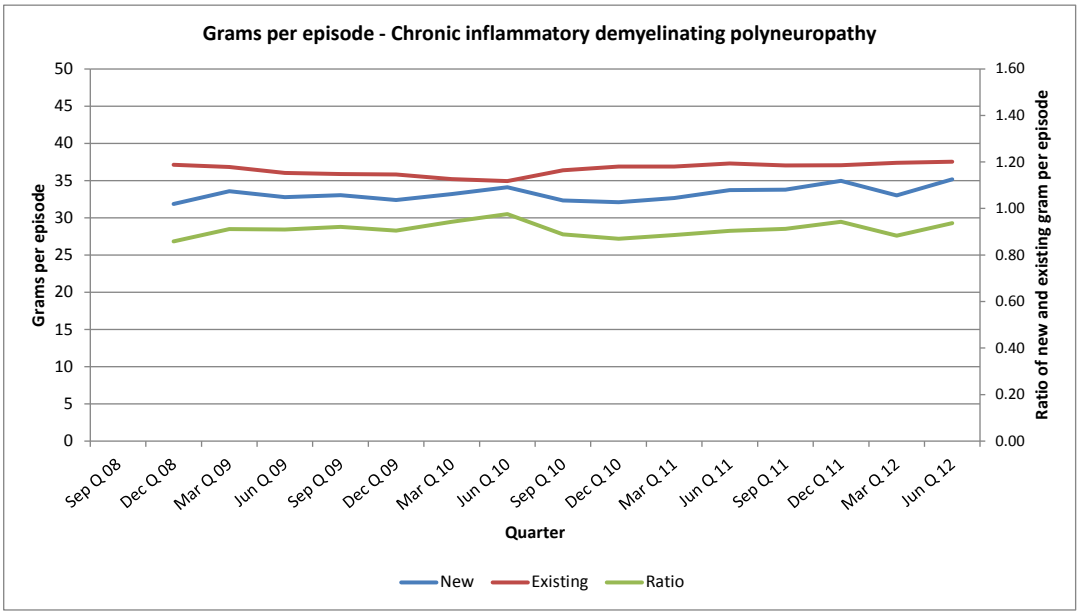

Figure 22 CIDP - new and existing - grams per episode (STARS)

Common variable immunodeficiency disease (CVID)

The following charts (Figure 23 and Figure 24) show the numbers and grams per episode for CVID. The largest numbers of new patients appear in the June quarter for the last three years. The increase over the sixteen quarters for CVID is 28% for patient numbers and 38% for total grams. The grams per episode are generally stable for existing patients. The grams per episode for new patients are more varied reflecting their low absolute numbers.

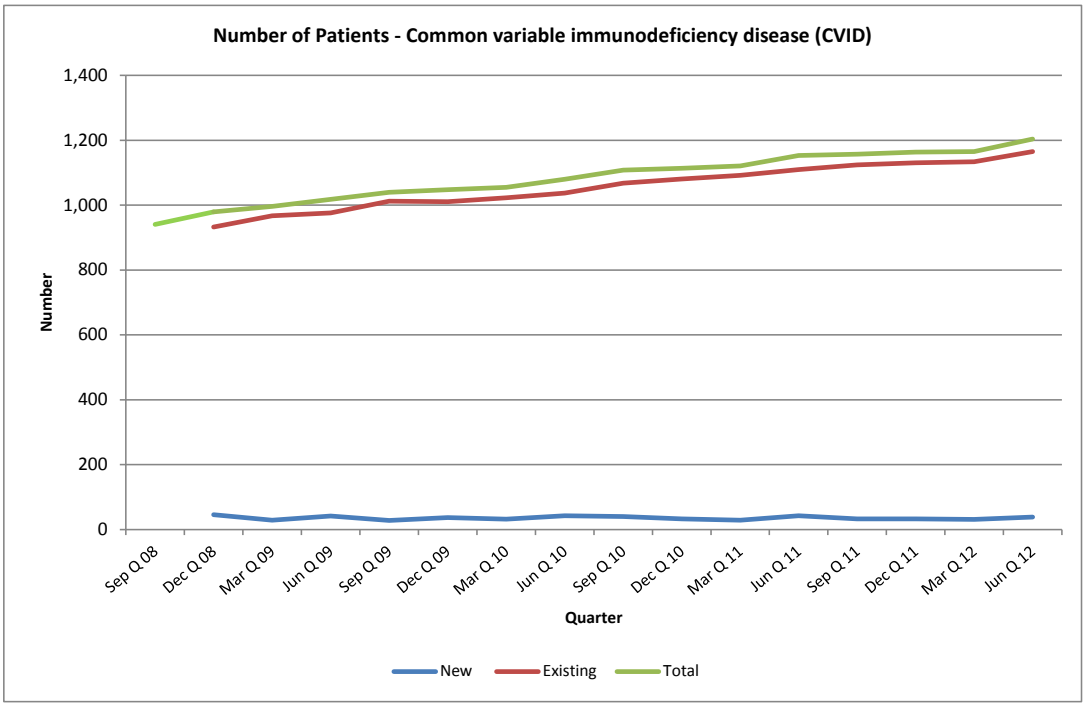

Figure 23 CVID - new and existing number of patients (STARS)

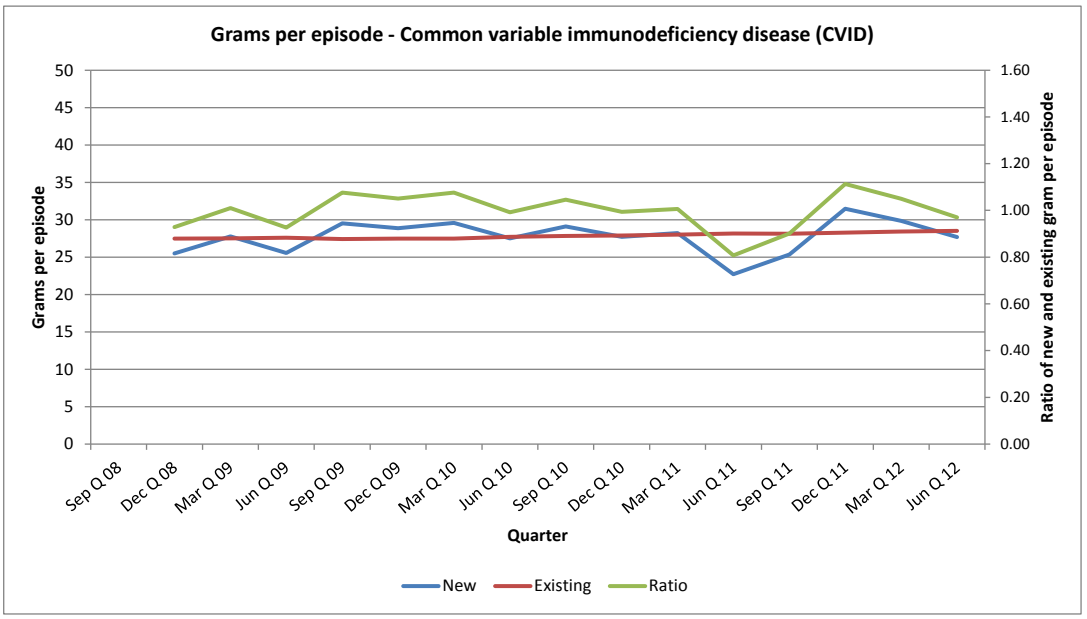

Figure 24 CVID - new and existing grams per episode (STARS)

Chronic lymphocytic leukaemia (CLL)

The increase over the sixteen quarters is 25% for numbers of patients and 35% for total grams.

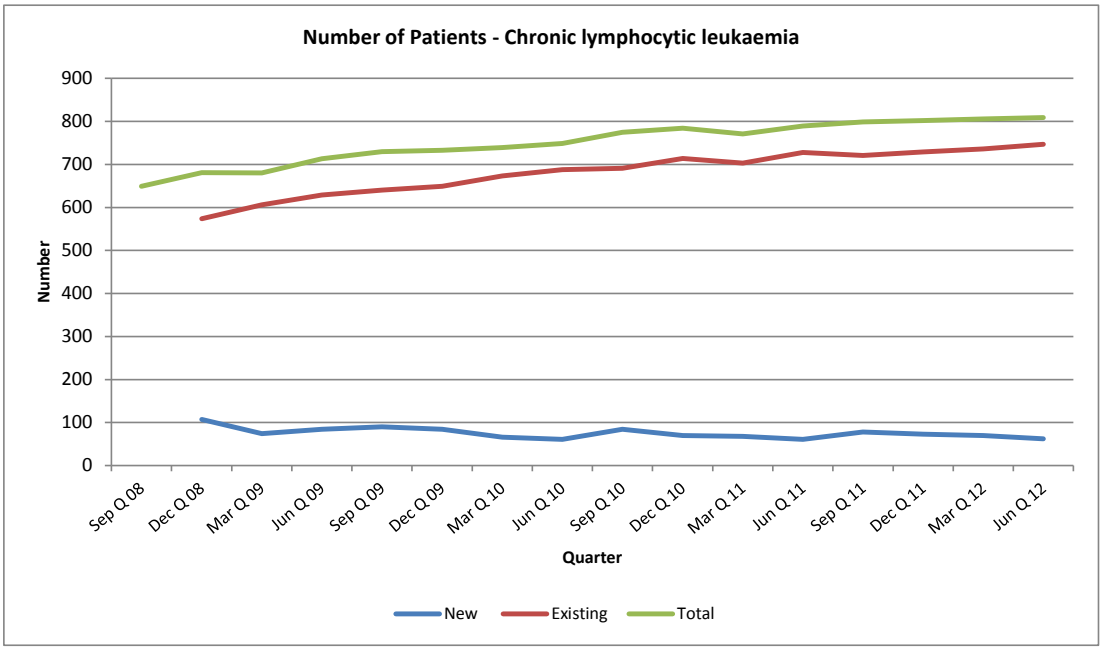

Figure 25 CLL - new and existing number of patients (STARS)

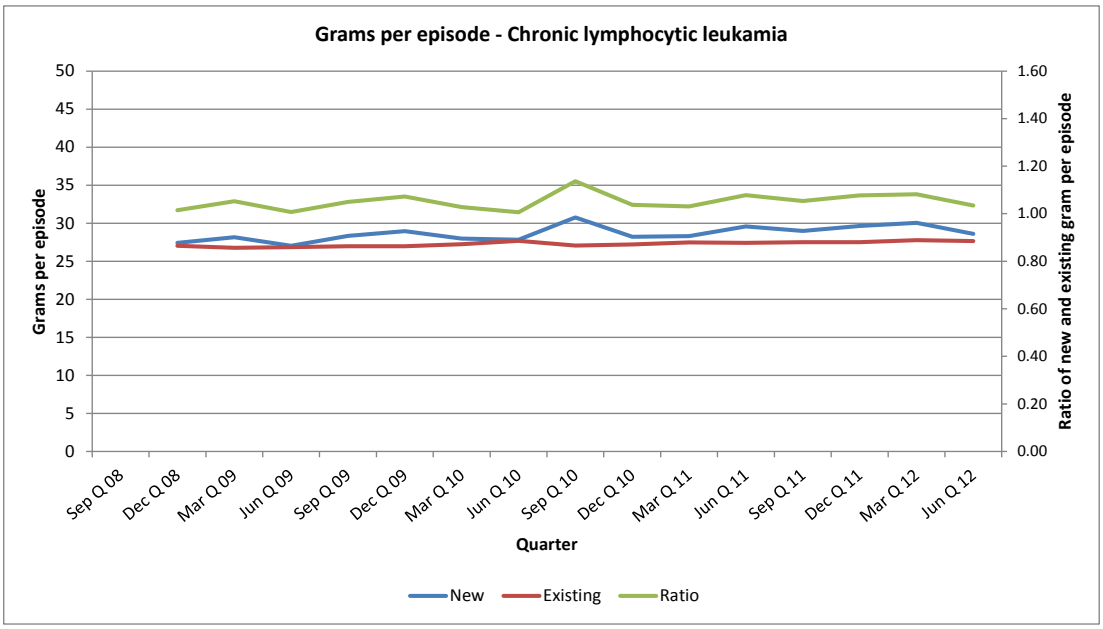

Figure 26 CLL - new and existing grams per episode (STARS)

Myasthenia gravis

The increase over the sixteen quarters is 86% for numbers of patients and 102% for total grams for this condition. The latter reflects a slight increase in the dose per episode interacting with the strong growth in numbers.

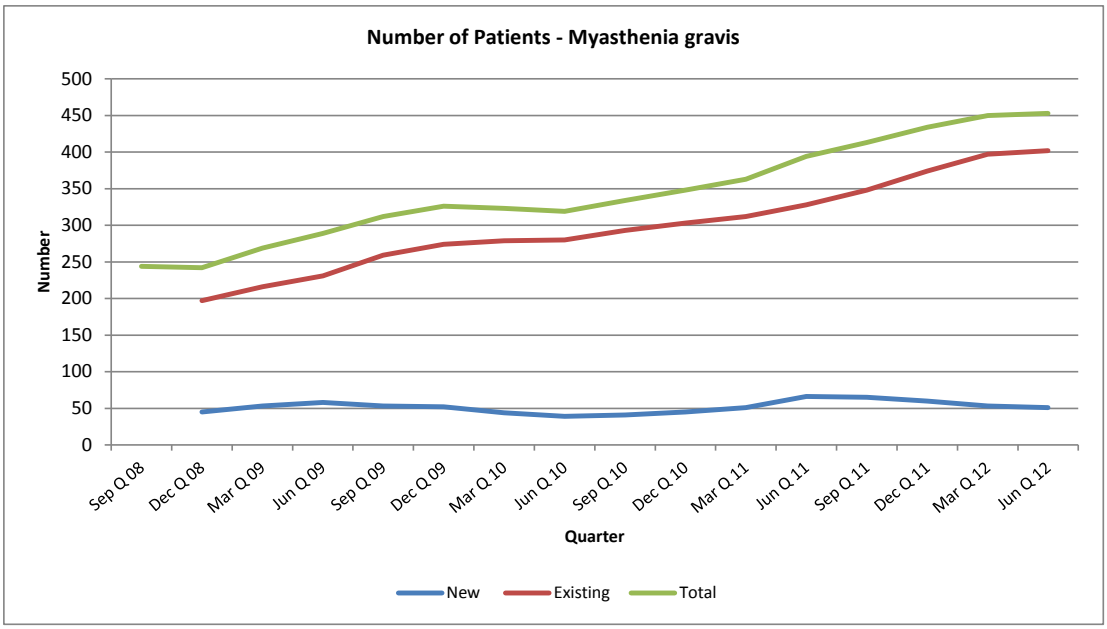

Figure 27 Myasthenia gravis - new and existing number of patients (STARS)

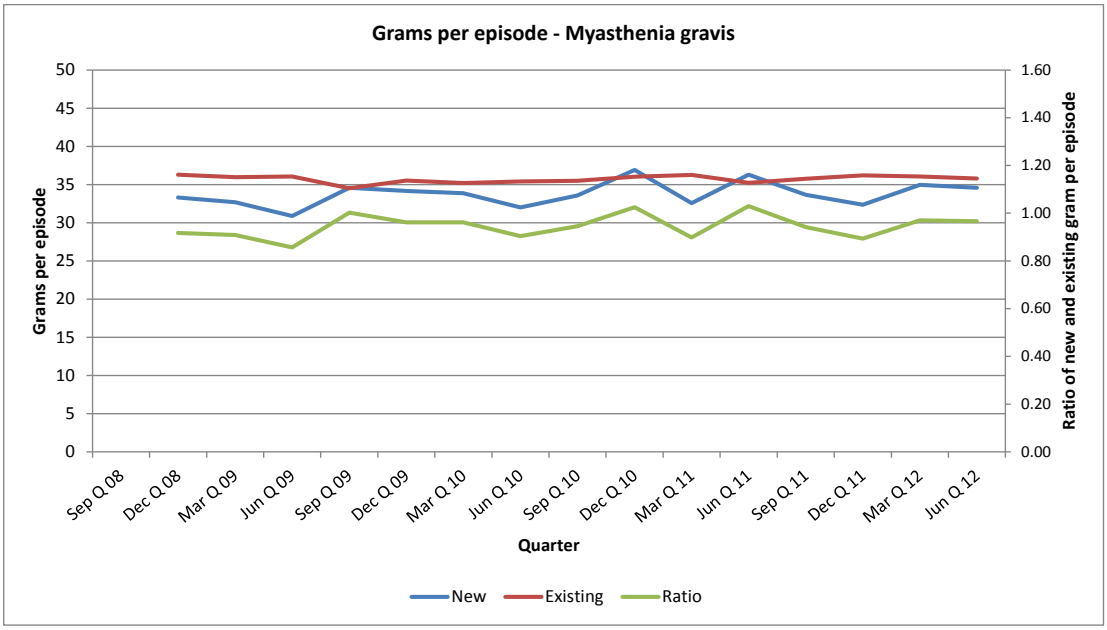

Figure 28 Myasthenia gravis - new and existing grams per episode (STARS)

Multiple myeloma

The increase over the sixteen quarters is 52% for numbers of patients and 60% for total grams for this condition. The latter reflects a slight increase in the dose per episode.

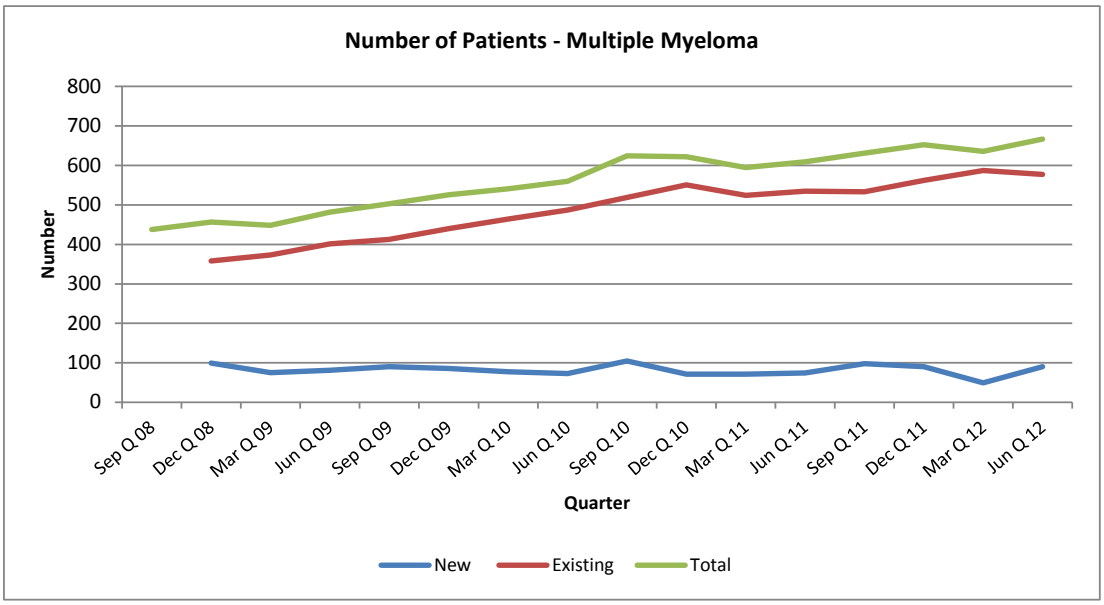

Figure 29 Multiple myeloma - new and existing number of patients (STARS)

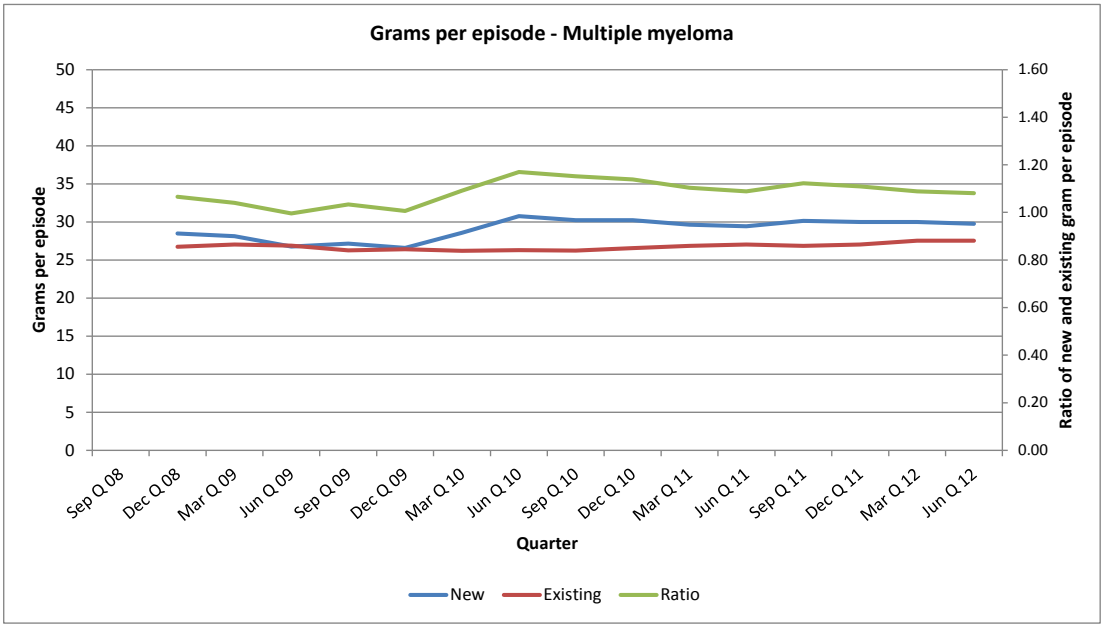

Figure 30 Multiple myeloma - new and existing grams per episode (STARS)

DIFFERENCE IN USE BETWEEN STATE AND TERRITORIES - SELECTED INDICATIONS

In this section grams issued per treatment episode for the five indications for which the greatest amount of IVIg was issued over the last two financial years are compared between states and territories as presented below.

The small states and territories have very small numbers of patients so results should be taken cautiously. Patients receiving product in two or more states and territories are counted in both states and territories. The Australian total however counts unique patients nationally.

Chronic inflammatory demyelinating polyneuropathy (CIDP)

Figure 31 shows the grams issued per treatment episode for the different states and territories for CIDP. There are differences between the dosing of the different states and territories. NSW and QLD have 'grams per episode' about 10% below the Australian average whereas SA and WA have 'grams per episode' about 20% above.

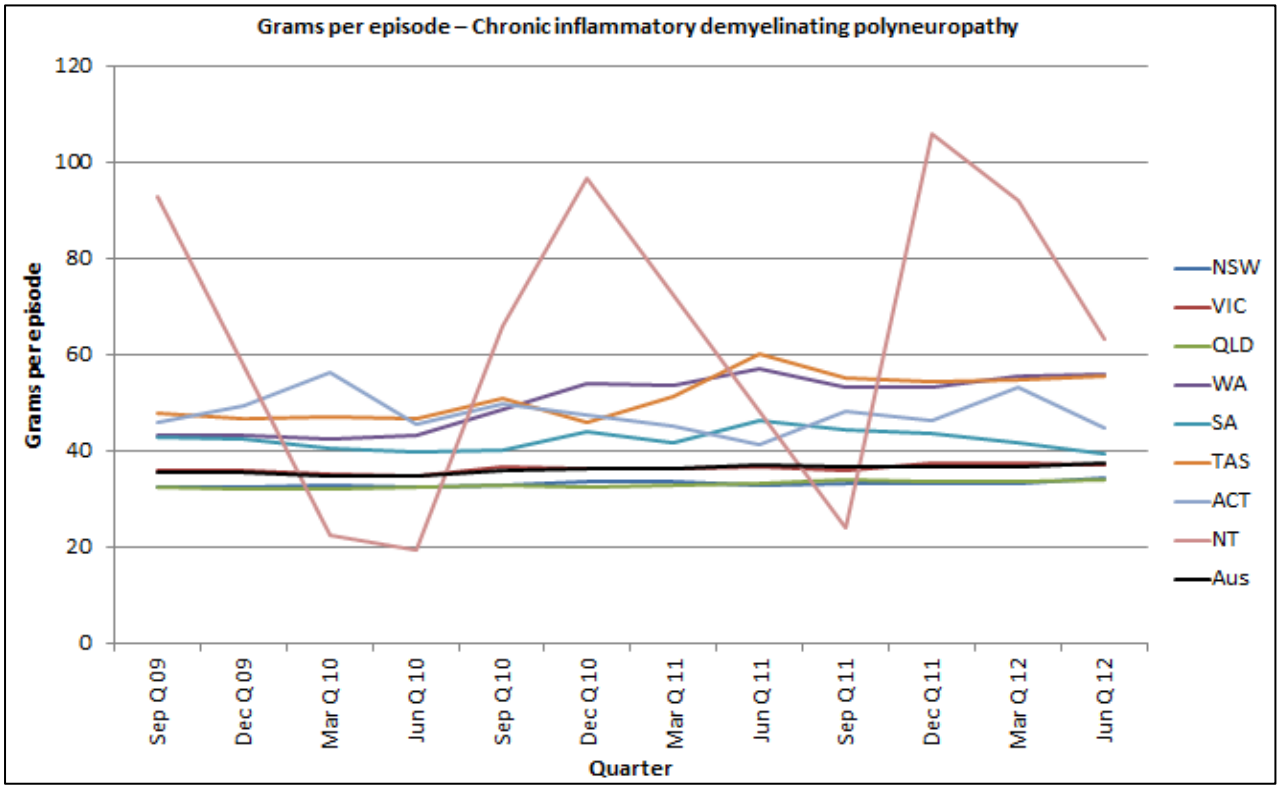

Figure 31 CIDP grams per episode (STARS)

QTR	Sep 09	Dec 09	Mar 09	Jun 10	Sep 10	Dec 10	Mar 11	Jun 11	Sep 11	Dec 11	Mar 12	Jun 12
NSW	390	386	408	418	421	432	443	442	456	468	495	489
VIC	245	254	249	253	253	252	266	273	277	295	299	303
QLD	189	200	219	210	208	225	222	241	255	277	285	314
WA	73	66	65	74	75	71	70	73	72	75	79	85
SA	44	49	49	50	49	46	49	52	51	50	56	58
TAS	32	32	33	31	29	32	30	24	26	26	27	26
ACT	12	11	11	13	12	12	13	11	11	12	13	14
NT	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5
AUST	**986**	**998**	**1,036**	**1,051**	**1,049**	**1,071**	**1,093**	**1,116**	**1,149**	**1,204**	**1,257**	**1,293**

Table 19 Patient numbers for CIDP (STARS)

Common variable immunodeficiency disease (CVID)

For CVID Figure 32 shows that most of the states and territories are clustered below the Australian average while NSW is higher.

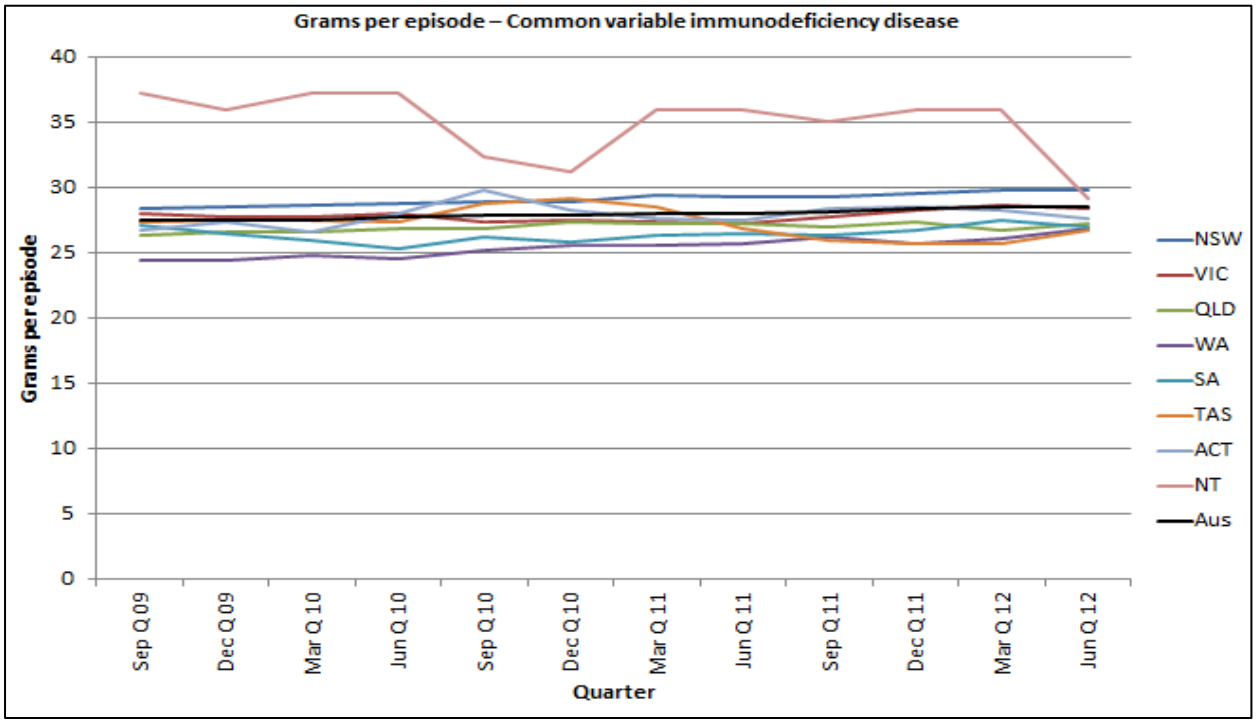

Figure 32 CVID grams per episode (STARS)

QTR	Sep 09	Dec 09	Mar 09	Jun 10	Sep 10	Dec 10	Mar 11	Jun 11	Sep 11	Dec 11	Mar 12	Jun 12
NSW	450	456	469	484	498	502	500	510	518	528	529	533
VIC	181	179	181	186	193	192	195	200	204	199	190	202
QLD	219	220	220	218	223	223	225	232	230	229	240	261
WA	66	60	55	54	53	53	55	54	55	54	54	53
SA	84	87	89	91	94	92	96	97	92	91	89	92
TAS	14	15	15	15	15	16	16	17	16	18	18	19
ACT	31	31	33	36	36	40	43	46	45	48	51	50
NT	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5
AUST	**1,047**	**1,051**	**1,064**	**1,086**	**1,116**	**1,121**	**1,131**	**1,157**	**1,163**	**1,169**	**1,172**	**1,213**

Table 20 Total patient numbers for CVID (STARS)

Chronic lymphocytic leukaemia (CLL)

For CLL Figure 33 shows most of the larger states are clustered around the Australian average.

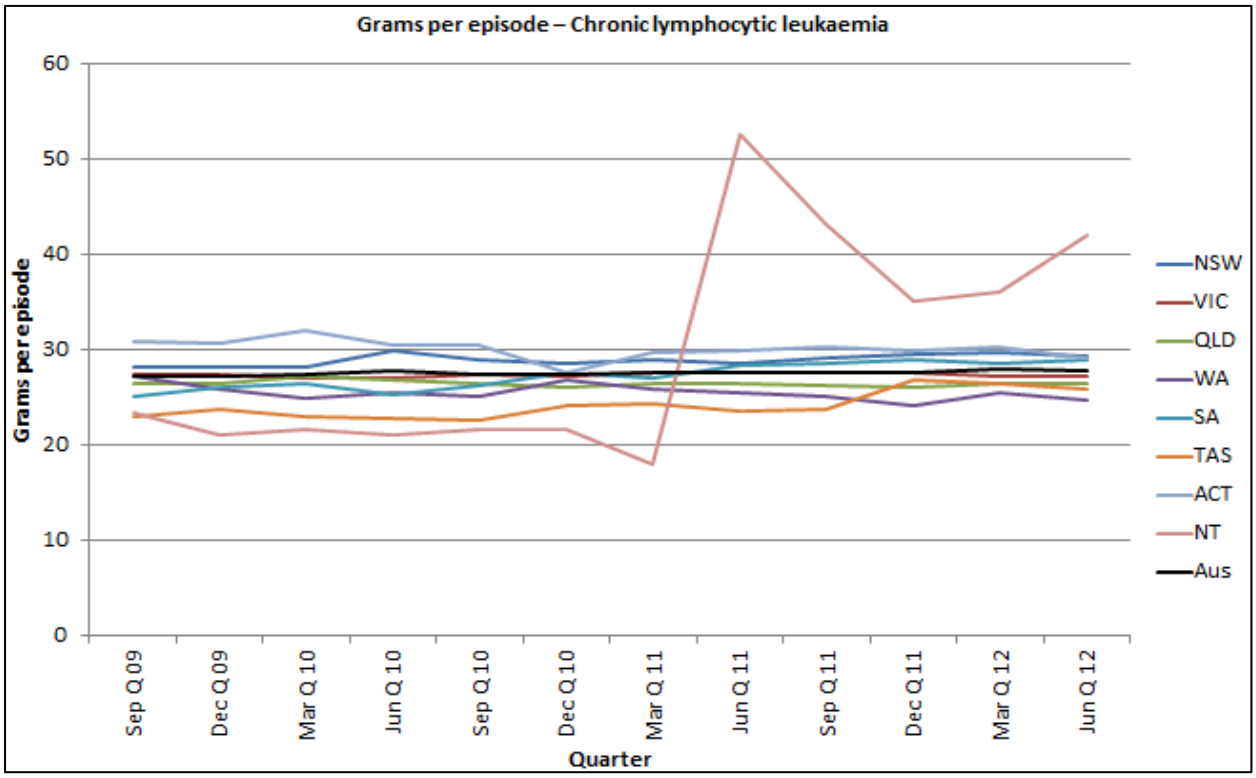

Figure 33 CLL grams per episode (STARS)

QTR	Sep 09	Dec 09	Mar 09	Jun 10	Sep 10	Dec 10	Mar 11	Jun 11	Sep 11	Dec 11	Mar 12	Jun 12
NSW	254	271	284	280	285	271	272	283	282	254	271	284
VIC	161	168	168	165	167	176	171	176	165	161	168	168
QLD	212	205	207	212	222	221	227	223	235	212	205	207
WA	23	27	29	25	23	31	35	30	33	23	27	29
SA	61	62	56	50	55	60	58	58	54	61	62	56
TAS	23	25	25	26	25	23	22	20	21	23	25	25
ACT	16	19	17	15	14	18	18	19	18	16	19	17
NT	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5	<5
AUST	**752**	**779**	**788**	**774**	**793**	**802**	**805**	**810**	**811**	**752**	**779**	**788**

Table 21 Total patient numbers for CLL (STARS)

Myasthenia gravis

Figure 34 shows a higher level of variability in dosing between states and territories for myasthenia gravis than the other conditions analysed. The numbers of patients for this condition are quite small and this may explain the divergence.

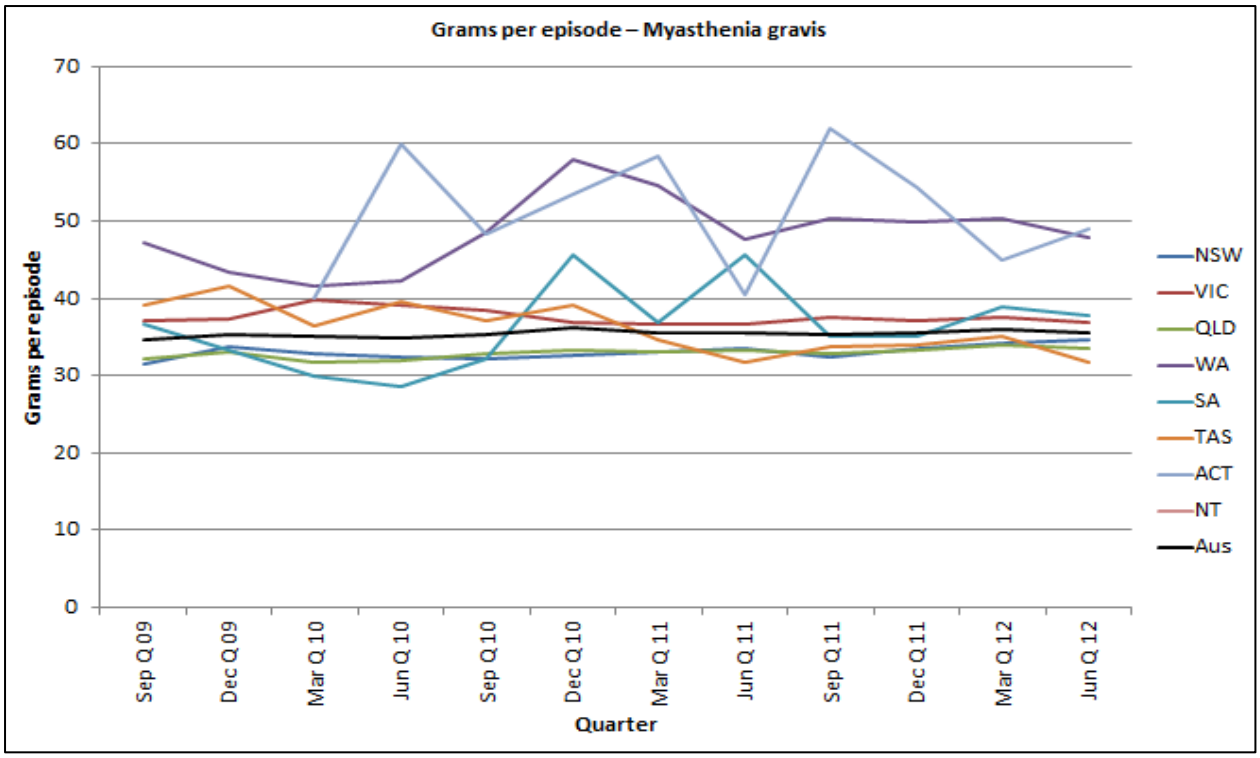

Figure 34 Myasthenia gravis grams per episode (STARS)

QTR	Sep 09	Dec 09	Mar 09	Jun 10	Sep 10	Dec 10	Mar 11	Jun 11	Sep 11	Dec 11	Mar 12	Jun 12
NSW	120	129	133	128	126	132	136	141	154	165	171	158
VIC	65	66	71	73	70	75	82	88	90	85	91	103
QLD	80	90	79	78	91	94	97	109	118	130	140	140
WA	23	21	21	21	23	27	28	25	29	28	20	21
SA	16	11	9	10	10	9	8	16	9	10	13	14
TAS	10	10	9	9	11	10	10	11	10	11	13	12
ACT			<5	<5	<5	<5	<5	<5	<5	7	6	8
NT												
AUST	**314**	**327**	**323**	**320**	**334**	**349**	**363**	**394**	**413**	**436**	**454**	**456**

Table 22 Total patient numbers for myasthenia gravis (STARS)

Multiple myeloma

Figure 35 shows a SA, NSW and ACT were above the national average.

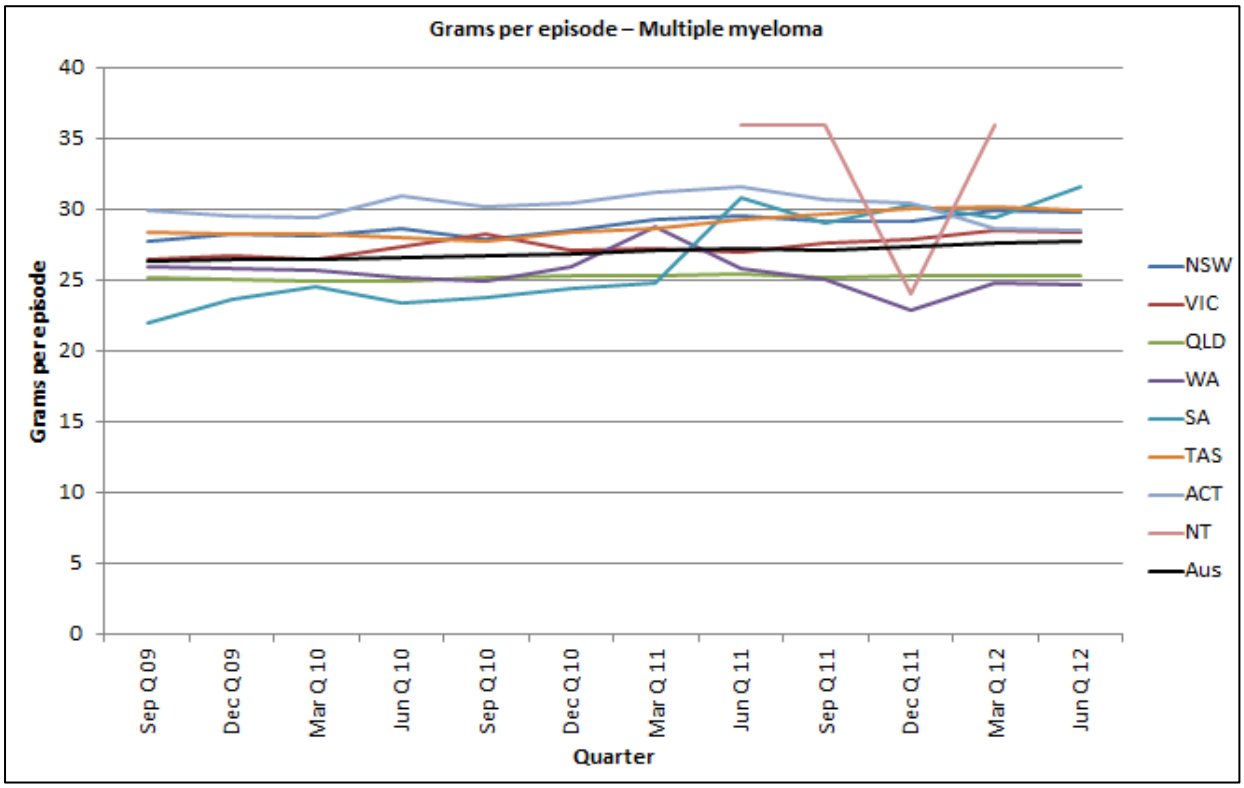

Figure 35 Multiple myeloma grams per episode (STARS)

QTR	Sep 09	Dec 09	Mar 09	Jun 10	Sep 10	Dec 10	Mar 11	Jun 11	Sep 11	Dec 11	Mar 12	Jun 12
NSW	157	176	173	177	192	194	174	190	213	215	216	237
VIC	71	67	81	81	103	106	107	95	89	97	88	102
QLD	213	217	215	230	244	250	245	252	261	266	263	258
WA	9	8	13	10	12	8	8	10	9	9	8	9
SA	10	15	15	13	12	9	6	7	8	10	10	13
TAS	37	35	37	40	44	42	44	42	40	45	42	41
ACT	7	10	10	10	17	14	14	12	11	9	8	9
NT								<5	<5	<5	<5	
AUST	**504**	**528**	**544**	**561**	**624**	**623**	**598**	**609**	**632**	**652**	**636**	**669**

Table 23 Total patient numbers for multiple myeloma (STARS)

TIME IN TREATMENT

Patients requiring IVIg may have a condition requiring only very short term IVIg treatments (e.g. Kawasaki's disease) or may suffer from a condition requiring chronic IVIg treatment, where it may be necessary to have IVIg for the rest of their lives. For each unique patient the estimated time in treatment is the number of days between the recorded first date when IVIg was issued and last date it was issued for that patient. A patient first recorded in the last quarter will have a maximum possible difference of about 90 days. In this calculation, a patient who has a chronic condition receiving IVIg since the first quarter of 2008-09 could have days in treatment of up to 730 days.
We have looked at the five conditions for which the largest volume of IVIg is issued and classified them as short term or long term.

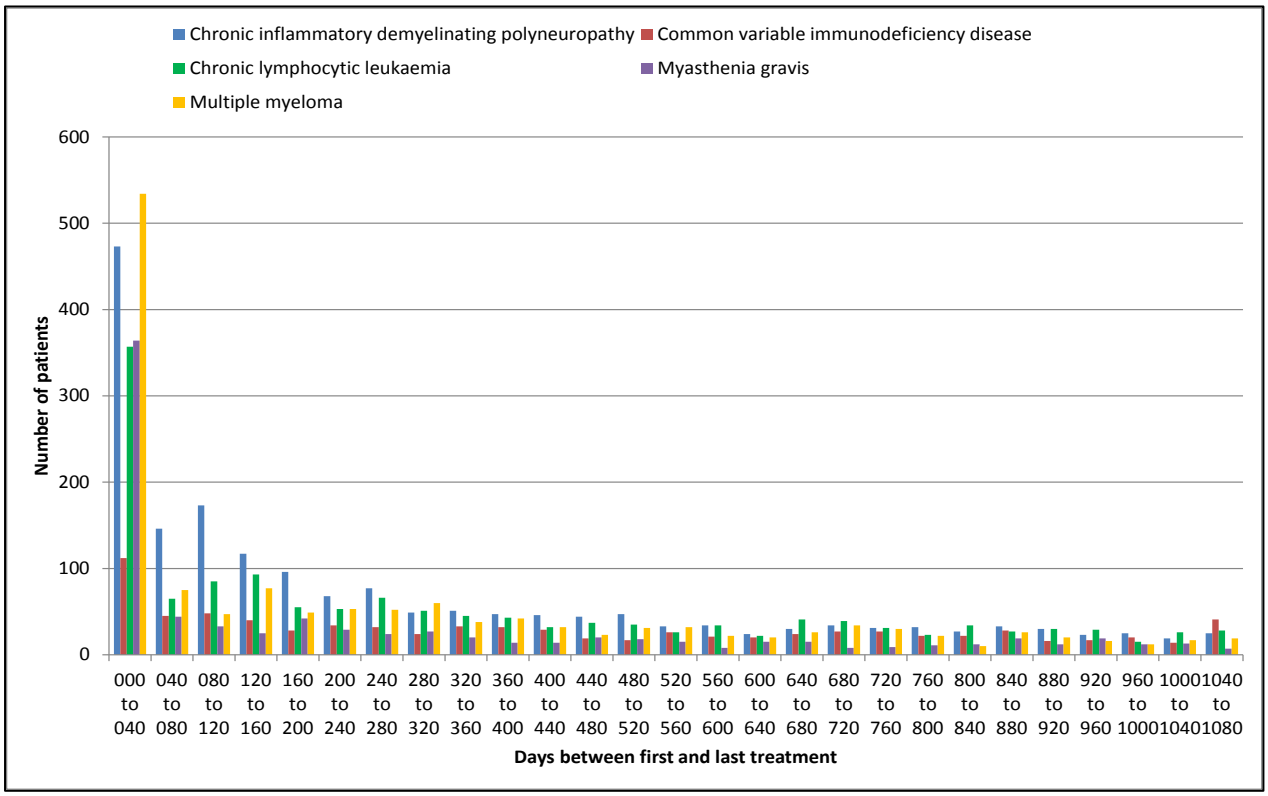

Figure 36 Days in treatment selected long term conditions (STARS)

The distributions shown in Figure 36 reflect a large number of patients that had IVIg throughout the period, the new patients joining in each quarter (most of whom continue to receive IVIg) and some patients that receive IVIg for a short period only despite their condition being of a longer term nature.

Note: Polymyositis, while it is treated in short term courses, is subject to relapses, which is reflected in the large numbers in the greater than 133 day category.

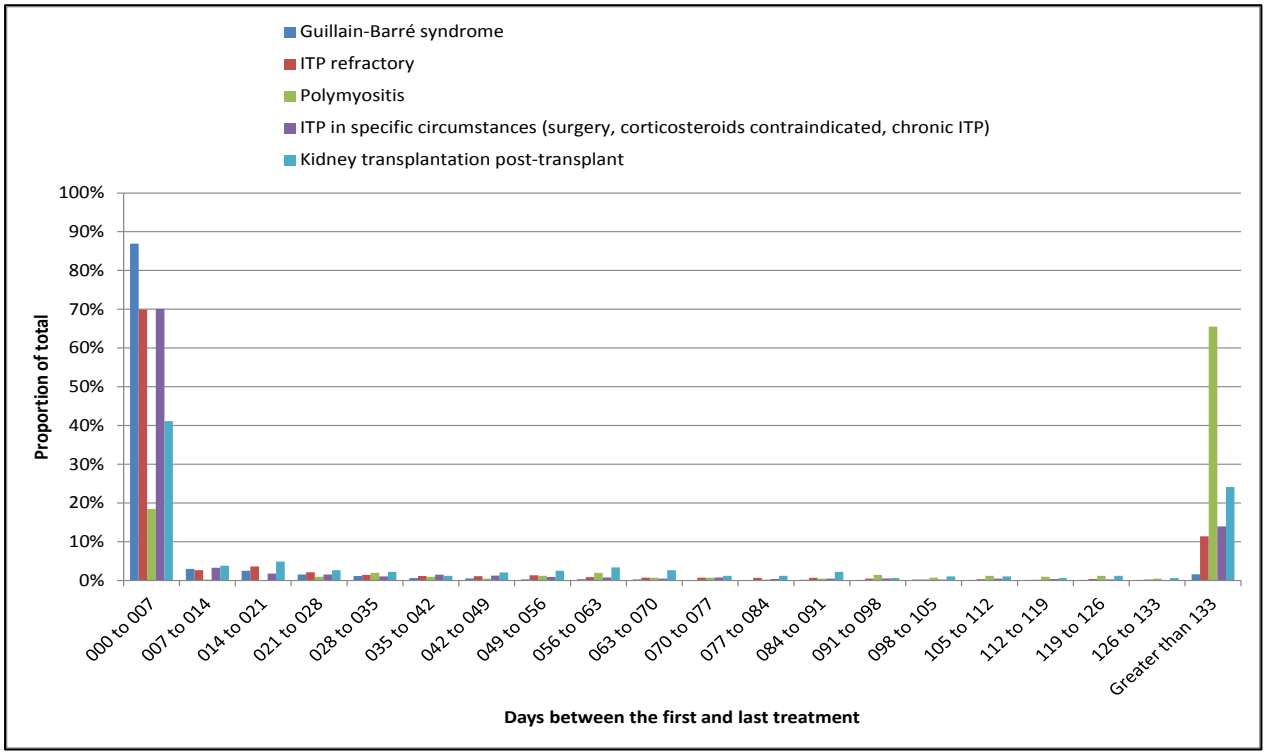

Figure 37 Days in treatment selected short term conditions (STARS)

For conditions considered short term, most patients receive treatment with IVIg for less than a week. Figure 38 shows the treatment periods for Kawasaki disease. The majority receive treatment with IVIg for only one day and a few receive additional treatments.

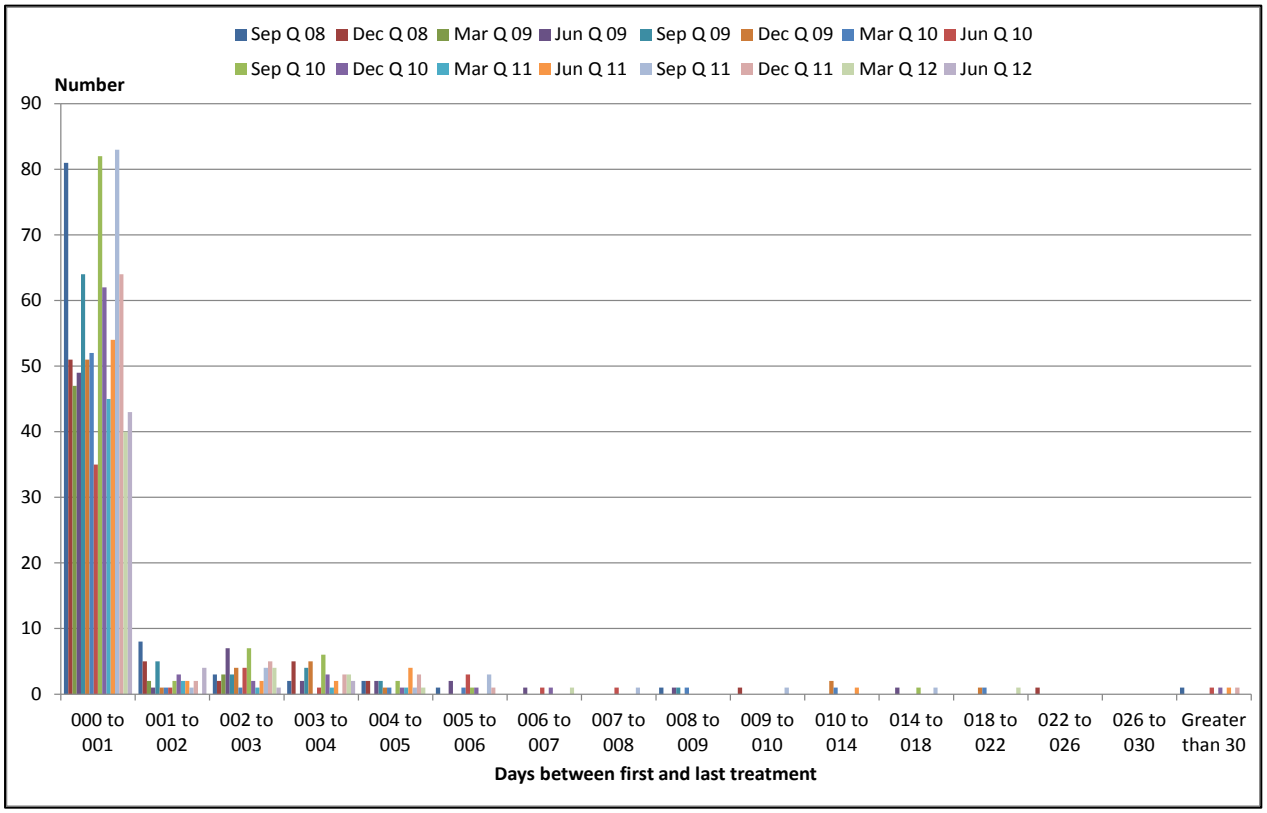

Figure 38 Days in treatment for Kawasaki disease by quarter of first joining (STARS)

Appendix A – Acronyms and Glossary

ACRONYMS

Acronym	Description
ACT	Australian Capital Territory
ABS	Australian Bureau of Statistics
Blood Service	Australian Red Cross Blood Service
CIDP	Chronic Inflammatory Demyelinating Polyneuropathy
CLL	Chronic Lymphocytic Leukaemia
Criteria	Criteria for the clinical use of intravenous immunoglobulin in Australia
CVID	Common Variable Immunodeficiency Disease
CTEPC	Clinical, Technical and Ethical Principal Committee
DO	Direct Order
IDMS	Integrated Data Management System
IgG	Immunoglobulin G
IVIg	Intravenous immunoglobulin
JBC	Jurisdictional Blood Committee
JDO	Jurisdictional Direct Order
NBA	National Blood Authority
NIg	Normal Immunoglobulin
NSW	New South Wales
NT	Northern Territory
QLD	Queensland
SA	South Australia
SCIg	Subcutaneous Immunoglobulin
STARS	Supply Tracking Analysis Recording System
TAS	Tasmania
TGA	Therapeutic Goods Administration
VIC	Victoria
WA	Western Australia

GLOSSARY OF TERMS

Term	Description
Alzheimer's disease	The most common form of dementia, a neurological disease resulting in impaired memory thinking and behaviour
Blood products	Products manufactured from donated blood
Blood Service	Australian Red Cross Blood Service
Condition	Clinical conditions categorised according to the quality of the available evidence and whether IVIg treatment is considered beneficial. Also known as the primary diagnosis
Criteria for the clinical use of intravenous immunoglobulin in Australia *or* *Criteria for Use*	Identifies the indications for which IVIg is funded under the national blood arrangements by all Australian governments; the book is not a medical or clinical guideline on treatment of the indications listed. Regular review of the *Criteria* is needed to align funded access to IVIg with the latest evidence, or in the case of limited evidence, a consensus of expert opinion
Criteria Not Met	Circumstances, based on evidence and clinical experience, under which the clinical use of IVIg is not considered appropriate to be funded in Australia
Direct Orders (DO)	Previously known as Jurisdictional Direct Orders (JDO). Arrangements implemented by the NBA with suppliers to facilitate the purchase of IVIg for the treatment of conditions not satisfying the *Criteria for the clinical use of IVIg in Australia*
DO Advised	Where Criteria Not Met, the requestor is advised that they can purchase the product through a Direct Order
DO Issued	Grams of IVIg issued under the Direct Order Arrangements
Disease Group	Grouping of primary diagnosis
Fractionation	Blood plasma fractionation refers to the general processes of separating the various components of blood plasma
Haemophilia A	Classic haemophilia: an inherited blood coagulation disorder that results from a quantitative deficiency of Factor VIII, a blood clotting protein necessary for normal coagulation
Haemophilia B	An inherited blood coagulation disorder similar to haemophilia A but caused by a quantitative deficiency of Factor IX
Immunodeficiency diseases	See http://www.nba.gov.au/ivig/pdf/criteria.pdf
Indefinite	Where Criteria Not Met, the requestor is advised will not met the Criteria
Integrated Data Management System	NBA business system containing data on supply and invoicing of blood products under NBA contracts
Intravenous immunoglobulin	Immunoglobulin administered intravenously (as opposed to intramuscular or sub-cutaneous injection), provided under the national blood arrangements to reduce susceptibility to infections

Term	Description
	and manage many immune system disorders
Issues	IVIg supplied under contracts managed by the NBA under the national blood arrangements
Jurisdiction (referred to as states and territories)	A signatory to the National Blood Agreement. This includes the Australian Government and all state and territory governments
National Blood Agreement	The Agreement signed by all governments in 2003 that sets out the objectives for governments for the management of the blood sector
National Blood Arrangement	The National Blood Authority was established on 1 July 2003 with the principal role of managing the national blood arrangements, ensuring sufficient supply and to provide a new focus on the safety and quality of blood and blood products
National Supply Plan and Budget	The national supply plan (including agreed volume of products and price list) to be supplied under the national blood arrangements approved by ministers
Treatment Episodes	Number of episodes recorded for that treatment – a patient may have one or many episodes of treatment
Pending	IVIg issued but not considered appropriate to be funded in Australia. May be awaiting diagnosis or pending a published resolution
Plasma	The liquid part of the blood and lymphatic fluid, which makes up approximately half of its volume. Blood plasma contains antibodies and other proteins. It is taken from donors and made into products for a variety of blood-related conditions
Primary Diagnosis	Clinical conditions categorised according to the quality of the available evidence and whether IVIg treatment is considered beneficial. Also known as condition
Supply Tracking Analysis Recording System	Database maintained by the Blood Service as contracted authoriser and distributor of IVIg products
Subcutaneous immunoglobulin	Immunoglobulin administered by injection into the layer of skin directly below the dermis and epidermis (as opposed to intravenous or intramuscular injection)

Appendix B – Background

Funding for IVIg

Guided by the National Blood Agreement policy objectives and aims, governments have agreed to provide IVIg under the National Blood Arrangements for the conditions and uses described in the latest edition of the *Criteria for the clinical use of intravenous immunoglobulin in Australia (Criteria)* in Chapter 5, Chapter 6 and Chapter 7 (conditions for which there is reasonable evidence and/or clinical support for the use of IVIg therapy). IVIg funded under the National Blood Arrangements is not available to treat conditions identified in Chapter 8. For conditions not described in Chapter 5, Chapter 6 or Chapter 7, Approved Recipients may obtain IVIg via the Jurisdictional Direct Order (JDO) component of the IVIg Standing Offer arrangements.

The Criteria

A process to review the Australian Health Ministers' Advisory Council (AHMAC) (2000) guidelines commenced in 2004. This led to the first edition of the Criteria being approved by Health Ministers in December 2007. The first addition of the *Criteria* was made available to clinicians on 3 March 2008 and applied to all new patients from that date. For patients already receiving IVIg for an indication not listed as being funded under the National Blood Agreement, a six month transition period was allowed to enable treatment strategies to be reviewed.

The *Criteria* for the clinical use of intravenous immunoglobulin in Australia is a book that describes the criteria that patients must meet to receive IVIg that is funded by all Australian governments. If patients meet the criteria, they do not have to pay for it. The *Criteria* helps to ensure that IVIg is accessed consistently across Australia for the treatment of patients whose health is likely to be improved with IVIg therapy. The *Criteria* was developed using the best available medical evidence and expertise.

As part of the process to implement the new *Criteria*, the NBA established a clarification process in November 2008. A consultation group was consulted on specific queries that arose in relation to interpretation of the *Criteria*. Consideration of the queries and comments resulted in some amendments to specific indications in the *Criteria*. The revisions were published on the NBA's website in February 2009.

In accordance with government commitments, JBC initiated a review of the *Criteria* in 2010. A National IVIg Criteria Review Working Group was established to oversee the 2010–11 Criteria Review process. The finalised *Criteria* document was endorsed by the JBC in December 2012. The *Criteria* second edition was made available to clinicians on 10 August 2012 and applied to all new patients from that date. For patients already receiving IVIg for an indication where the specific criteria have changed, a six month transition period was been allowed to enable treatment strategies to be reviewed.

Supply of Product

IVIg is an expensive therapy made from human plasma which is one component of human blood. Australia has not been able to make enough IVIg from Australian blood donations for a number of years. While NBA makes sure there is enough IVIg by importing this product, there is a finite international supply.

There are two main ways IVIg is available in Australia:

1. Supply under National Blood Arrangements

If the IVIg is ordered to treat a medical condition which is funded under the *Criteria* then the product is supplied and funded under the National Blood Arrangements. In this case the cost of the product is shared between the Commonwealth and the relevant state or territory.

Orders for IVIg under the National Blood Arrangements are made to the Blood Service, which is contracted by the NBA as the authoriser and distributor of all IVIg funded under these arrangements. In seeking authorisation, the requesting clinician will be asked to provide information to the Blood Service to establish that the request meets the *Criteria*. For ongoing conditions, the *Criteria* may specify review criteria to be applied in reviewing the patient to determine whether access to funded IVIg will continue.

In the role as authoriser of requests for IVIg, the Blood Service maintains a database of requests, and provides data to the NBA which is used as a basis for reporting on the annual use of IVIg in Australia.

2. Direct order and other supply arrangements

If the IVIg is to treat a medical condition which is not funded under the *Criteria*, then the individual state or territory may approve the accessing of product under the direct order arrangements established by the NBA, or the product may be ordered directly from a commercial supplier of IVIg. In this case the supply of the product is not funded under the National Blood Arrangements, and the cost must be met in some other way.

History

In **2003-04** the NBA coordinated demand management activities for two products in short supply; Biostate (plasma-derived Factor VIII) and Intragam P (plasma-derived IVIg). At all times, the NBA successfully met the blood and blood product needs of all Australian jurisdictions through intensive management of the product, via its contracts with the Blood Service and CSL Limited and the importation of substitutable products from overseas. The NBA arranged for an imported product to be purchased to make up for the shortfall, and this product was made available to patients in March 2004.

In **2004-05** the NBA successfully negotiated a new Plasma Products Agreement with CSL Limited which came into effect from 1 January 2005.

In December 2004 the NBA also signed a Standing Offer contract with CSL Limited (for the supply of Sandoglobulin), as well as with Octapharma Australia Pty Ltd (for the supply of Octagam) for a two-year period in order to allow access to imported IVIg as a contingency supply if and when needed to supplement shortfalls in the domestic IVIg supply. The IVIg Standing Offer comprised two components, a National Blood Supply component whereby imported IVIg was procured by the NBA for use under the National Blood Agreement (i.e. for those conditions covered under the nationally agreed cost sharing arrangements) and a Jurisdictional Direct Order component which allowed approved recipients to access imported IVIg for all other conditions.

IVIg had to be intensively managed again in 2004–05 due to ongoing increases in demand and indications for its clinical use for over 60 clinical syndromes and conditions.

As part of a strategic solution to the shortage of IVIg, governments purchased imported IVIg (Sandoglobulin) in 2003 and placed it in the National Reserve of Plasma Products. In order to optimise the use of the stocks in the National Reserve, the NBA in conjunction with jurisdictions, the Blood Service and CSL Limited, developed and implemented a plan to rotate the Sandoglobulin stocks out of the National Reserve. This rotation commenced in October 2004.

In **2005-06**, the challenges in supply of domestic IVIg required the NBA to adopt the same intensive product management arrangements as it had in 2004-05 with the continued rotation of Sandoglobulin.

In **2006-07** in order to ensure IVIg remained available to all Australians, the National Blood Authority negotiated a further 12-month extension to the IVIg Standing Offer in December 2006. A procurement process for the renewal of the standing offer arrangements commenced in early 2007.

Intensive management was successfully undertaken in 2006–07 to avert a number of temporary and longer-term potential shortages, including shortages of IVIg and plasma-derived Factor VIII.

In **2007-08** the NBA commenced a procurement process for new contracts in mid-2007. The outcome of the procurement was the finalisation of a new fixed price contract with Octapharma Australia Pty Ltd for the supply of Octagam for three years under the National Blood Supply arrangement. Octagam and a CSL Ltd imported product, Sandoglobulin Liquid, were also supplied under Direct Order (DO) arrangements negotiated by the NBA.

In **2008-09** the NBA continued imports of intravenous immunoglobulin to allow us to fully meet domestic clinical demand.

During **2009–10** the plasma fractionation arrangements were governed by the five-year Plasma Products Agreement between the NBA and CSL Limited, which expired on 31 December 2009, and a new CSL Australian Fractionation Agreement which took effect on 1 January 2010.

The contract with Octapharma Australia Pty Ltd for the supply of Octagam was due to expire on 31 December 2010, with the NBA having an option to extend the contract by one year. In May 2010 the NBA moved to exercise the option to extend the current contract with Octapharma Australia Pty Ltd, with improved value for money, for a further 12 months.

A contract with CSL Limited for the supply of Sandoglobulin NF (nanofiltration) Liquid under the Jurisdictional Direct Order arrangement expired at the end of December 2009.

The NBA entered into a three-year contract with Lateral Grifols Pty Ltd for the supply of Flebogamma 5% DIF (dual inactivation plus nanofiltration) under Direct Orders, which commenced on 1 January 2010.

During **2010-11** imported intravenous immunoglobulin continued to supplement domestic IVIg production to meet clinical demand in Australia. In September 2010, Octapharma issued a nationwide voluntary recall of Octagam due to production concerns. To enable domestic demand to be met, the NBA invoked relevant clauses which had been included in the contract with Lateral Diagnostics to allow supply of Flebogamma through the national blood arrangements (in addition to the Direct Orders supply). Lateral Diagnostics, working with the Spanish-based manufacturer of Flebogamma, Grifols S.A., responded rapidly and fully to the NBA's additional requirements and this arrangement continued for the remainder of the year. The voluntary recall of Octagam was still in place in Australia at 30 June 2011.

In **2011-12** as a result of a significant drop in its immunoglobulin (IgG) yield due to factors related to the plasma collection program of the Blood Service. As a result of the reduction in yield, and other logistical factors, CSL Limited was unable to supply Intragam P 200ml from its working inventory against the full annual supply estimate amounts. The NBA also gave approval for CSL Limited to access the Minimum Product Inventory and the National CSL Reserve to augment supply. By the end of June 2012 CSL Limited had fully restocked the Minimum Product Inventory and the National CSL Reserve, although the NBA continued to carefully manage the planned supply of Intragam P in 2012-13.

The Therapeutic Goods Administration (TGA) approved the re-introduction of Octagam 5% in October 2011 following the voluntary recall of product in September 2010. The NBA worked with the Blood

Service, Octapharma Australia Pty Ltd and Grifols Australia Pty Ltd to manage the transition of patients from Flebogamma 5 % DIF under the national supply arrangements; this was achieved by March 2012.

In October 2011 the NBA signed contracts for the supply of imported IVIg with Octapharma Australia Pty Ltd for the supply of Octagam 5%. The new contract took effect on 1 January 2012. A 10% formulation of this product became available in July 2012; Baxter Healthcare Pty Ltd for the supply of Kiovig 10 per cent from 1 January 2012 and with Grifols Australia Pty Ltd for a direct order contract operating until 31 December 2012 for the supply of Flebogamma 5 per cent DIF. A new direct order contract for continued supply of Flebogamma 5 per cent commenced on 1 January 2012.

Appendix C – IVIg grams per 1000 population 2011-12 by state and territory and primary diagnosis

Disease Category	Primary Diagnosis	NSW	VIC	QLD	WA	SA	TAS	ACT	NT	Grand Total
Chapter 5	CIDP	30.0	33.1	32.9	28.8	18.1	37.9	19.2	7.6	30.1
	CLL	11.8	9.1	14.8	3.5	10.6	12.0	15.9	3.4	10.7
	CVID	24.9	12.7	17.6	8.0	16.8	11.9	49.1	3.2	17.9
	Dermatomyositis	1.6	1.3	0.6	0.8	1.9	4.6	2.5	0.0	1.3
	Guillain-Barré syndrome	4.7	4.6	3.7	4.0	3.6	2.0	5.1	2.0	4.2
	Hypogammaglobulinaemia Unclassified	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Inclusion body myositis	1.9	1.3	1.3	0.0	1.3	3.6	0.0	0.0	1.4
	ITP associated with HIV	0.0	0.0	0.0	0.0	0.1	0.2	0.0	0.0	0.0
	ITP in pregnancy	0.4	0.3	0.5	0.8	1.1	0.1	0.7	0.8	0.5
	ITP in specific circumstances (surgery, corticosteroids contraindicated, chronic ITP)	2.5	2.9	3.2	1.7	2.4	3.7	0.9	0.8	2.6
	ITP refractory	2.3	2.5	4.6	2.2	3.4	3.1	2.4	6.0	3.0
	ITP with life-threatening haemorrhage	2.2	0.3	0.5	0.0	2.5	0.0	2.8	0.0	1.1
	Kawasaki disease	0.6	0.6	0.3	0.4	0.4	0.4	0.5	0.2	0.5
	Lambert-Eaton myasthenic syndrome	0.3	0.3	0.7	0.1	0.0	0.0	0.0	0.0	0.3
	Multifocal motor neuropathy with persistent conduction block	8.8	7.3	7.7	12.1	10.8	1.9	2.2	17.9	8.5
	Multiple myeloma	9.0	4.9	17.2	0.8	1.9	27.5	8.2	1.1	8.6
	Myasthenia gravis	9.9	10.0	15.7	7.4	3.1	11.0	12.2	0.0	10.3
	Neonatal haemochromatosis	0.0	0.1	0.5	0.0	0.0	0.0	0.0	0.0	0.1
	Non-Hodgkin lymphoma	7.1	5.7	18.2	1.2	5.9	11.3	15.9	0.0	8.4

Disease Category	Primary Diagnosis	NSW	VIC	QLD	WA	SA	TAS	ACT	NT	Grand Total
	Other primary immunodeficiency	1.9	2.0	0.5	1.3	0.5	0.6	0.2	2.3	1.4
	Other relevant haematological malignancies	4.7	2.9	3.3	0.7	0.9	2.9	2.4	2.2	3.2
	Polymyositis	6.1	3.1	5.1	0.8	3.2	3.1	1.6	0.0	4.1
	Severe combined immunodeficiency	0.0	0.5	1.5	0.0	0.0	0.0	0.0	0.0	0.4
	Stiff person syndrome	0.7	0.8	1.9	0.0	0.2	1.3	0.0	0.3	0.9
	Wiskott-Aldrich syndrome	0.0	0.0	0.1	0.2	0.0	0.0	0.0	0.0	0.1
	X-linked agammaglobulinaemia	0.8	3.0	1.3	0.8	1.2	0.0	0.4	0.0	1.4
Chapter 5 Total		**132.1**	**109.5**	**153.7**	**75.6**	**89.8**	**139.2**	**142.3**	**47.7**	**121.2**
Chapter 6	Acute disseminated encephalomyelitis	0.4	0.2	0.1	0.0	0.0	0.3	0.0	0.0	0.2
	ANCA (PR3 or MPO)-positive idiopathic rapidly progressive glomerulonephritis	0.1	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.1
	Autoimmune haemolytic anaemia	0.7	0.6	0.8	0.3	0.7	0.2	0.4	0.0	0.6
	Bullous pemphigoid	0.5	0.2	0.2	0.3	0.1	0.0	1.9	0.0	0.3
	Cicatricial pemphigoid	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0
	Evans syndrome	0.5	0.1	0.6	0.0	0.0	0.0	4.8	0.0	0.4
	Foeto-maternal /neonatal alloimmune thrombocytopenia (Antenatal)	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1
	Foeto-maternal /neonatal alloimmune thrombocytopenia (Neonatal)	0.2	0.8	0.5	0.2	1.5	0.0	0.0	0.0	0.5
	Haemophagocytic syndrome	0.0	0.0	0.0	0.0	0.2	0.0	0.0	0.0	0.0
	HSCT (for prevention of GvHD in high risk Allogeneic HSCT).	0.2	0.2	0.4	0.0	0.0	0.0	0.0	0.0	0.2
	IgG subclass deficiency existing patients only	0.3	1.9	7.4	0.0	3.4	0.0	0.0	0.0	2.3
	IgM para-proteinaemic neuropathy	4.7	1.8	1.1	0.6	2.4	4.4	0.8	0.0	2.5
	ITP in children	0.6	0.4	1.3	1.0	0.5	0.0	0.0	0.0	0.7
	Kidney transplantation post-transplant	0.1	0.3	0.4	0.2	0.5	0.1	0.3	0.0	0.3
	Kidney transplantation pre-transplant	1.2	6.4	2.6	0.9	1.1	3.6	0.2	2.7	2.8
	Microscopic polyangiitis	0.3	1.0	0.1	0.0	0.3	0.0	0.0	0.0	0.4

Disease Category	Primary Diagnosis	NSW	VIC	QLD	WA	SA	TAS	ACT	NT	Grand Total
	Multiple sclerosis - severe relapse with no response to high dose methylprednisolone	0.1	0.0	0.1	0.2	0.0	0.0	0.0	0.0	0.1
	Multiple sclerosis in pregnancy	0.1	0.2	0.6	0.0	0.1	0.2	0.0	0.0	0.2
	Multiple sclerosis in young patients severe/relapsing/remitting in whom other therapies have failed	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Opsoclonus myoclonus ataxia	0.1	0.1	0.1	0.0	0.1	0.0	0.0	0.0	0.1
	Pemphigus foliaceus	0.2	0.1	0.0	0.0	0.4	0.0	0.0	0.0	0.1
	Pemphigus vulgaris	0.4	0.3	0.1	0.0	0.0	0.0	0.0	0.0	0.2
	Post transfusion purpura	0.8	0.1	1.0	0.5	0.9	0.0	3.4	0.0	0.7
	Secondary hypogammaglobulinaemia (excludes haem malignancies)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Specific antibody deficiency	4.0	3.1	7.9	1.8	1.2	12.6	0.5	0.4	4.2
	Toxic epidermal necrolysis/Steven Johnson syndrome	1.7	1.1	2.1	3.8	1.5	0.8	7.2	0.9	1.9
	TSS - staphylococcal	0.4	0.6	0.1	0.1	0.1	0.5	0.0	0.7	0.3
	TSS - streptococcal	0.2	0.1	0.1	0.1	0.0	0.4	0.0	0.0	0.1
	Wegener's granulomatosis	0.1	0.0	0.0	0.1	0.2	0.0	0.0	0.0	0.1
Chapter 6 Total		**18.5**	**20.4**	**28.0**	**10.4**	**15.3**	**23.3**	**19.7**	**7.5**	**19.8**
Chapter 7	Acute leukaemia in children	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Autoimmune congenital heart block	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Autoimmune diabetic neuropathy	0.1	0.1	0.0	0.0	0.1	0.5	0.0	0.0	0.1
	Autoimmune neutropenia	0.3	0.0	0.1	0.2	0.1	0.0	0.0	0.0	0.2
	Catastrophic antiphospholipid syndrome	0.2	0.0	0.2	0.0	0.1	0.0	3.0	0.0	0.2
	Coagulation factor inhibitors	0.1	0.0	0.1	0.0	0.5	0.0	0.0	1.1	0.1
	Devic disease (neuromyelitis optica)	0.4	0.0	0.2	0.0	0.0	0.0	0.0	0.0	0.2
	Epidermolysis bullosa acquisita	0.0	0.0	0.0	0.4	0.0	0.9	0.0	0.0	0.1
	Epilepsy (rare childhood cases)	0.1	0.9	1.1	0.0	0.5	0.1	0.9	0.0	0.5

Disease Category	Primary Diagnosis	NSW	VIC	QLD	WA	SA	TAS	ACT	NT	Grand Total
	Graves' ophthalmopathy	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Haemolytic disease of the newborn	0.2	0.2	0.4	0.0	0.0	0.0	0.1	0.0	0.2
	Haemolytic transfusion reaction	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Myocarditis in children	0.0	0.0	0.0	0.0	0.1	0.0	0.0	0.0	0.0
	Paraneoplastic syndromes	0.5	0.4	0.7	0.7	0.7	0.8	0.2	0.0	0.6
	Potassium channel antibody-associated encephalopathy	1.2	1.1	0.7	0.5	0.7	0.2	0.0	0.0	0.9
	Pure red cell aplasia	0.1	0.1	0.5	0.1	0.0	3.0	0.0	0.0	0.3
	Pure white cell aplasia	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0
	Scleromyxedema	0.9	0.2	0.0	0.1	0.0	0.0	0.0	0.0	0.3
	Sepsis - neonatal	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Sjogren's Syndrome	0.3	0.0	0.2	0.2	0.7	0.0	2.2	0.0	0.2
	Solid organ - heart	0.0	0.0	0.2	0.1	0.0	0.0	0.0	0.0	0.1
	Solid organ - heart/lung	0.1	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0
	Solid organ - liver	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Solid organ - lung	0.6	0.2	0.6	0.2	0.3	1.0	0.0	0.0	0.4
	Solid organ - other	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Susac syndrome	0.2	0.0	0.4	0.0	0.0	0.0	0.0	0.0	0.1
Chapter 7 Total		**5.4**	**3.4**	**5.5**	**2.6**	**4.0**	**6.4**	**6.4**	**1.2**	**4.5**
Chapter 8	Asthma	0.0	0.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Atopic dermatitis/eczema	0.0	0.0	0.0	0.2	0.0	0.0	0.0	0.0	0.0
	Systemic lupus erythematosus	0.0	0.0	0.0	0.2	0.0	0.0	0.0	0.0	0.0
Chapter 8 Total		**0.0**	**0.2**	**0.0**	**0.4**	**0.0**	**0.0**	**0.0**	**0.0**	**0.1**
Chapter DO	**DO issue**	**0.0**	**0.0**	**0.0**	**0.0**	**0.1**	**0.0**	**0.0**	**0.0**	**0.0**
Grand Total		**155.9**	**133.5**	**187.2**	**88.9**	**109.3**	**168.9**	**168.4**	**56.4**	**145.6**

Appendix D – IVIg average gram per episode by state and territory and primary diagnosis

Disease Category	Primary Diagnosis	NSW	QLD	SA	VIC	TAS	WA	ACT	NT	Grand Total
Chapter 5	CIDP	33.0	36.1	32.8	48.4	43.1	51.9	47.3	49.7	36.1
	CLL	28.6	27.2	26.5	25.4	27.0	23.6	29.8	27.7	27.4
	CVID	28.9	27.7	26.9	25.0	26.5	27.2	27.9	34.6	27.8
	Dermatomyositis	29.1	41.3	30.3	53.6	40.8	67.4	48.0		35.8
	Guillain-Barré syndrome	31.9	32.8	30.1	66.8	41.6	40.5	33.1	76.8	34.0
	Hypogammaglobulinaemia Unclassified		70.0							70.0
	Idiopathic thrombocytopenic purpura - Adult			27.5						27.5
	Inclusion body myositis	33.1	34.1	35.6	62.1	34.9	38.1	72.0		34.5
	ITP associated with HIV	29.1	49.6	34.9	80.0	70.0	85.0	96.1		38.8
	ITP in pregnancy	39.6	52.1	31.4	65.0	55.5	47.0	75.6	54.3	43.1
	ITP in specific circumstances (surgery, corticosteroids contraindicated, chronic ITP)	36.7	54.1	31.1	61.8	58.9	61.3	81.0	73.6	40.8
	ITP refractory	37.2	52.4	31.5	64.3	59.3	53.2	71.1	76.8	41.0
	ITP with life-threatening haemorrhage	38.7	55.3	36.1	77.6	59.8	71.3	60.9	52.0	42.4
	Kawasaki disease	32.7	30.9	33.5	32.6	32.3	27.1	34.1	24.4	32.1
	Lambert-Eaton myasthenic syndrome	34.0	39.1	27.7	62.7	225.0			39.0	33.9
	Multifocal motor neuropathy with persistent conduction block	34.7	39.7	31.0	57.8	52.4	34.1	29.2	89.6	39.2
	Multiple myeloma	28.7	27.4	25.4	26.1	25.8	29.0	32.3	35.1	27.0
	Myasthenia gravis	33.1	37.1	32.7	48.4	36.8	38.9	48.5		35.3
	Neonatal haemochromatosis	73.7	59.4	66.6	62.9	3.0				65.5

Disease Category	Primary Diagnosis	NSW	QLD	SA	VIC	TAS	WA	ACT	NT	Grand Total
	Non-Hodgkin lymphoma	28.4	29.2	25.6	28.7	26.9	26.0	28.9	36.0	27.1
	Other primary immunodeficiency	26.2	28.4	22.3	23.9	34.6	24.3	15.9	20.8	26.6
	Other relevant haematological malignancies	27.9	27.8	25.1	21.2	22.3	27.2	28.6	31.1	26.8
	Polymyositis	31.5	43.5	34.1	51.1	45.7	60.4	37.2	40.1	35.6
	Severe combined immunodeficiency	11.6	19.1	25.6		3.0				23.0
	Stiff person syndrome	41.5	41.3	61.1	66.0	41.5	35.5		21.0	48.0
	Wiskott-Aldrich syndrome	16.4	11.1	24.9	25.7	14.3	33.0			21.4
	X-linked agammaglobulinaemia	22.7	26.9	25.1	22.5	26.4	27.0	13.2		25.3
Chapter 5 Total		**31.0**	**33.1**	**29.0**	**41.5**	**35.7**	**35.6**	**32.8**	**50.2**	**31.9**
Chapter 6										
	Acute disseminated encephalomyelitis	31.8	30.7	28.3	40.4	37.2	30.0	3.0		31.8
	ANCA (PR3 or MPO)-positive idiopathic rapidly progressive glomerulonephritis	34.1	28.1	25.3	38.6					30.5
	Autoimmune haemolytic anaemia	35.7	53.3	31.8	65.3	51.4	79.1	75.7		40.2
	Bullous pemphigoid	56.3	59.4	27.4	48.3	170.0		120.0		51.3
	Churg-Strauss syndrome	29.3			147.0					55.4
	Cicatricial pemphigoid	74.8	113.2	46.8				65.8		63.4
	Evans syndrome	31.9	51.0	18.5	55.3	68.5		35.0		30.6
	Foeto-maternal /neonatal alloimmune thrombocytopenia (Antenatal)	71.1	64.4	70.8	73.4	59.3	3.4	6.0		52.2
	Foeto-maternal /neonatal alloimmune thrombocytopenia (Neonatal)	10.4	28.3	3.1	3.2	51.8	3.0		5.5	28.4
	Haemophagocytic syndrome	38.2	45.1	33.8	9.0	27.4	47.0			38.4
	HSCT (for prevention of GvHD in high risk Allogeneic HSCT).	27.7	31.0	23.8	27.3	37.7				26.1
	IgG subclass deficiency existing patients only	27.0	27.3	21.0	25.9	29.3	26.0	22.8		26.4
	IgM para-proteinaemic neuropathy	31.5	36.4	33.3	54.7	28.0	120.0			35.5

Disease Category	Primary Diagnosis	NSW	QLD	SA	VIC	TAS	WA	ACT	NT	Grand Total
	ITP in children	23.6	25.4	26.5	28.6	29.1	14.4	26.8	40.1	26.2
	Kidney transplantation pre-transplant	35.3	24.6	16.6	26.5	18.7				25.8
	Kidney transplantation post-transplant	24.9	33.5	16.9	61.9	21.7	51.5	38.0	53.0	29.6
	Microscopic polyangiitis	38.3	36.7	22.7	49.3					35.9
	Multiple scelorosis - severe relapse with no response to high dose methylprednisolone	34.9	25.2	32.9		30.0	38.9			31.2
	Multiple sclerosis in pregnancy	28.1		30.0						28.5
	Multiple sclerosis in young patients severe/relapsing/remitting in whom other therapies have failed	26.5	30.9	28.3		73.5	34.7			29.6
	Opsoclonus myoclonus ataxia	27.6	16.8	29.8	22.4	32.3	27.5			23.7
	Pemphigus foliaceus	58.1	79.2	55.0						62.4
	Pemphigus vulgaris	53.3	61.4	44.8	125.0	92.0		96.7		58.2
	Post transfusion purpura	48.3	64.3	35.0	75.0	27.6				47.9
	Secondary hypogammaglobulinaemia (excludes haem malignancies)	26.0	26.7	24.2	18.7	22.9	35.7	32.4	35.7	25.2
	Specific antibody deficiency	24.0	26.8	20.8	23.3	25.6	28.3	21.6	9.0	23.4
	Toxic epidermal necrolysis/Steven Johnson syndrome	46.9	68.4	38.2	97.4	78.6	67.7	22.8	76.8	57.8
	TSS - staphylococcal	67.1	54.0	54.4	85.7	80.0	54.0	66.3	88.0	62.6
	TSS - streptococcal	75.8	81.9	62.4	126.6	65.6	142.6	62.3	137.0	76.0
	Wegener's granulomatosis	30.8	35.6	38.5	71.8	24.5	111.0			36.6
Chapter 6 Total		**29.4**	**33.2**	**25.1**	**30.0**	**32.1**	**30.5**	**31.2**	**29.7**	**29.1**
Chapter 7										
	Acute leukaemia in children	10.5	14.8	12.7	15.0	12.0	5.0			12.5
	Autoimmune congenital heart block		62.5	60.0						61.1
	Autoimmune diabetic neuropathy	22.2	49.4	30.0		19.9	77.4			41.0
	Autoimmune neutropenia	56.0	45.5	33.2	55.3	100.0				46.9

Disease Category	Primary Diagnosis	NSW	QLD	SA	VIC	TAS	WA	ACT	NT	Grand Total
	Catastrophic antiphospholipid syndrome	41.3	47.7	32.2	66.0	66.7		88.7		44.0
	Coagulation factor inhibitors	45.5	57.6	31.4	45.8	43.7			80.5	41.3
	Devic disease (neuromyelitis optica)	31.8	31.6	24.3	71.7		30.0			30.5
	Epidermolysis bullosa acquisita				67.5		75.0			68.7
	Epilepsy (rare childhood cases)	32.1	38.6	30.8	33.6	48.3	48.0	53.0		34.9
	Graves' ophthalmopathy	35.0	45.0							38.4
	Haemolytic disease of the newborn	18.1	15.7	77.3	3.0	3.2	3.0	2.9	3.0	23.3
	Haemolytic transfusion reaction	30.0	50.0		85.0			3.0		36.8
	Myocarditis in children	24.8	22.5	44.1	45.6	17.8				31.1
	PANDAS/tic disorders	86.7	49.2			42.6				55.3
	Paraneoplastic syndromes	30.9	31.7	26.0	58.8	33.5	19.6	32.7		32.9
	Potassium channel antibody-associated encephalopathy	30.1	35.3	30.8	59.5	39.2	27.0	30.6		33.5
	Pure red cell aplasia	39.6	41.1	36.5	35.0	39.3	39.5			38.3
	Pure white cell aplasia			26.5						26.5
	Scleromyxedema	61.7	21.3	35.4	101.4			36.0		41.3
	Sepsis - neonatal	3.1	3.2	4.1	3.0	3.0	3.0		3.0	3.2
	Sjogren's Syndrome	30.1	37.3	25.8	46.0	116.7		34.2		41.7
	Solid organ - heart	23.0	37.7	20.6	145.0	18.0				26.3
	Solid organ - heart/lung	35.7	36.0	28.0	110.0	35.5				33.0
	Solid organ - liver	40.8	19.4	21.4						26.7
	Solid organ - lung	34.4	29.7	26.9	66.2	44.4	30.1		120.0	32.5
	Solid organ - other		25.6	11.9						13.6
	Solid organ - pancreas		7.5							7.5
	Susac syndrome	32.0	41.8	49.2						38.8
Chapter 7 Total		**31.8**	**30.6**	**32.9**	**47.5**	**43.4**	**43.7**	**32.5**	**47.8**	**33.8**
Chapter 8										

Disease Category	Primary Diagnosis	NSW	QLD	SA	VIC	TAS	WA	ACT	NT	Grand Total
	Asthma		38.4							38.4
	Atopic dermatitis/eczema			27.0						27.0
	Female infertility		27.0							27.0
	Lupus nephritis				143.3					143.3
	Paraneoplastic cerebellar degeneration (Yo antibodies)				102.5					102.5
	Sepsis (other than neonatal sepsis)		56.9							56.9
	Systemic lupus erythematosus				39.0					39.0
Chapter 8 Total			**38.7**	**27.0**	**49.9**					**40.8**
Chapter DO	**DO issue**		**35.3**	**40.0**	**11.5**	**38.3**				**31.1**
Grand Total		**30.8**	**33.1**	**28.4**	**39.6**	**35.3**	**35.0**	**32.6**	**47.2**	**31.6**

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